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Megadyne, Inc.

Clinical Evaluation Report

Megadyne Class I Accessory Products
CER # SCN070740, A

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TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

This clinical evaluation is based on a comprehensive analysis of available nonclinical data relevant to the intended purpose of the Megadyne Class I Accessory Products (subject devices). The Megadyne Class I Accessory Products are intended for to be used adjunctively as accessory devices for other Class IIa and IIb devices described in Section 4.2 (which are not in scope of this CER). This CER demonstrates that the subject devices conform to the European Council Directive 93/42/EEC Medical Device Directive (MDD) as amended by 2007/47/EC. The Megadyne Class I Accessory Products have been available collectively in the EU for over 20 years with initial CE Mark certification on 13 January 1999 and US FDA clearance on 24 January 2014 (see Table 1).

In accordance with MDD Annex X 1.1d and based on the risk management output and the detailed risk analysis performed on the Megadyne Class I Accessory Products, it was objectively determined and confirmed that clinical data is neither appropriate nor required to establish safety and performance of these Class I, non-sterile, non-patient contacting accessory devices. Conformity with all applicable Essential Requirements was appropriately based on functional safety and performance testing to all applicable standards. Conformance with pre-determined device specifications and applicable standards was conducted and fully demonstrated.

As the non-clinical route of conformance is utilized per Annex X 1.1d, there are no clinical safety or performance endpoints relative to the patient. There are however, specific non-clinical tests which are summarized in section 6.2.

The body of evidence from safety and performance testing supports that the subject devices are functioning as intended and that the risks of use of the Megadyne Class I Accessory Products are outweighed by the benefits for patients and health care professionals.

Based on the data appraisal and analysis in this report as informed by the Risk Management, and in accordance with EN ISO 14971, all residual risks are deemed acceptable when weighed against the benefits to the patient based on compliance with current specifications and applicable standards. Therefore, this clinical evaluation conforms with all applicable Essential Requirements. Since by definition, the utilization of a non-clinical route of conformity in accordance with MDD Annex X1.1d, clinical data and PMCF are not required since there are no safety or performance metrics on which to collect clinical data. Due to the risk evaluation of the subject device, the frequency of updates for the clinical evaluation is determined to be at least every 5 years (see section 8.2 for justification).

Refer to Appendix 9.1 for supporting documents referenced in the CER.

2. SCOPE

2.1. Objective

The objective of this clinical evaluation process is to establish conformity with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC. The planning and execution of the clinical evaluation is conducted in accordance with internal process “Clinical Evaluation Report Procedure” (PR-0000277).

This clinical evaluation report (CER) is an output of the process to document the collection, appraisal, and analysis of the available nonclinical data relevant to the subject devices and to determine whether there is sufficient nonclinical evidence on the safety and performance in accordance to the intended purpose. In addition, the report documents the benefit-risk profile including side-effects in the intended target patient populations and medical indications by assessing the nonclinical evidence against the hazards and patient harms as informed by the Risk Management and PMS documentation. The report also demonstrates the acceptability of that profile based on compliance with current specifications and applicable standards.

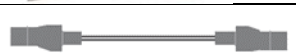
2.2. Subject Device Overview and Regulatory History

This clinical evaluation is a post-market CER covering 22 product codes within the Megadyne Class I Accessory Products family, which includes the device variants described in Table 1. The Megadyne Class I Accessory Products are classified in the EU under Annex IX Rule 1 of the European Council Directive 93/42/EEC (MDD) as a Class I non-sterile, non-invasive medical devices. The product classification was determined by considering the classification of non-invasive devices. These devices contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. They do not contact the patient and do not contain computer software.

The legal manufacturer is Megadyne, Inc., 11506 South State Street, Draper, Utah 84020 USA.

The subject devices have been collectively commercially available in the EU for over 20 years. As summarized in Table 1, the earliest MegaSoft Class I accessory device was CE Mark certified on 13 January 1999, the earliest MegaPower generator Class I accessory was CE Mark certified on 24 March 2005, and the earliest MegaVac Smoke Evacuator Class I accessory was CE Mark certified November 2003.

Table 1: Megadyne Class I Accessory Products Variants Covered within the CER

Product Code	Description	MDD Device Class	MDD Rule	Sterility	CE Mark Date	US Clearance Date	Technical Document	Representative Image [C]
0825	MEGA 2000™ Sheath	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K01	Mega Soft Reusable DetachaCable™ Cord, Standard Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K02	Mega Soft Reusable DetachaCable™ Cord, Standard Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K03	Mega Soft Reusable DetachaCable™ Cord, Phone Plug Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K04	Mega Soft Reusable DetachaCable™ Cord, Phone Plug Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K05	Mega Soft Reusable DetachaCable™ Cord, Extended Phone Plug Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K06	Mega Soft Reusable DetachaCable™ Cord, Argon Beam Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K07	Replacement Pigtail Cable	I	Rule 1	Non-Sterile	10APR2013	24JAN2014	RA-TECH-0003	
M2K08	DetachaCable™ Cord, Compatibility, Mega Soft 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	
M2K09	DetachaCable™ Cord, Compatibility, Mega Soft 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13JAN1999	24JAN2014	RA-TECH-0003	

Product Code	Description	MDD Device Class	MDD Rule	Sterility	CE Mark Date	US Clearance Date	Technical Document	Representative Image [C]
PKIT001	MEGA SOFT™ Patch Kit	I	Rule 1	Non-Sterile	23OCT2002	24JAN2014	RA-TECH-0003	
0075	Reusable Foot Control Cable, 3 m (10 ft)	I	Rule 1	Non-Sterile	12May2005 [A]	See regulatory history on file	RA-TECH-0007	
1300SJ	Mega Cart with Top Shelf	I	Rule 1	Non-Sterile	12May2005 [A]	24MAR2005	RA-TECH-0007	
1300U	Mega Cart	I	Rule 1	Non-Sterile	12May2005 [A]	24MAR2005	RA-TECH-0007	
1400J	Monopolar Footswitch (3 m cable)	I	Rule 1	Non-Sterile	12May2005 [A]	24MAR2005	RA-TECH-0007	
1450J	Bipolar Footswitch (3 m cable)	I	Rule 1	Non-Sterile	12May2005 [A]	24MAR2005	RA-TECH-0007	

Product Code	Description	MDD Device Class	MDD Rule	Sterility	CE Mark Date	US Clearance Date	Technical Document	Representative Image [C]
2140J	MegaVac Connector	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	
2145J	22mm Male to 10mm Male Connector	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	
2150J	Universal Connector	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	
2151J	22mm ID Tube Connector	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	
2211J	Ulpa Filter	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	
2220J	Charcoal Filter (MEGA VAC™)	I	Rule 1	Non-Sterile	NOV2003 [B]	18FEB2015 [B]	RA-TECH-0002	

Table Footnotes

A *Date of Mega Power regulatory clearance.*

B *Date of MegaVac regulatory clearance*

C The images provided are for illustration purposes only and do not represent all device specifications.

2.3. Current Clinical Evaluation Route of Conformity

The Megadyne Class I accessory devices have been collectively available in EU for over 20 years with earliest CE Mark certification in 1999. The clinical evaluation route of conformity (ROC) was determined during the planning stage (Stage 0) through the Clinical Evaluation Plan (CEP) and continuously evaluated through the execution stage (Stage 1-3).

Clinical data is neither applicable nor required for these Class I accessory devices. Therefore, in accordance with Per Annex X, 1.1d of the European Council Directive 93/42/EEC (MDD), the body of evidence used to demonstrate conformity with the Essential Requirements and support the safety and performance of these accessory devices includes non-clinical data, risk management outputs, and PMS data. Justification for using this non-clinical route of conformity is based on a review of the output risk management process, having considered the specifics of the device/body interaction for these EU class I non-sterile accessory devices which have no direct contact with the patient. Further, there are no clinical claims which would require clinical trials or clinical trial data for these low risk devices.

3. STATE OF THE ART

3.1. State of the Art Methods and Results

The Megadyne Class I Accessory Products are low risk class I devices which are using a non-clinical route of conformity. MEDDEV 2.7/1 Revision 4 requires these low risk accessory subject devices to be compared to the State-of-the-Art in order to confirm safety and performance and defines State-of-the-Art as:

*The current knowledge/state of the art in the corresponding medical field, such as **applicable standards** and guidance documents, information relating to the medical condition managed with the device and its natural course, benchmark devices, other devices and medical alternatives available to the target population.*

Given that the subject device accessories are all low risk class I accessory devices used adjunctively with other Class IIa and IIb devices, which are not in scope of this CER, conformance with State-of-the-Art is demonstrated through compliance and passing of non-clinical tests which have predefined acceptance criteria and conformance with all applicable standards in accordance with MEDDEV 2.7/1 revision 4.

The Class I subject device accessory products only provide an indirect adjunctive role in supporting other electrosurgery and ultrasonic surgery devices and are not directly used to treat specific clinical diseases or conditions. Therefore, it is not possible to focus on a specific clinical disease. Hence, the following sections will provide an overview of the technology in which these other electrosurgical devices belong and a broad discussion of the surgical needs these technologies address, as well as the pathologies that might necessitate use of electrosurgery procedures where the Class I accessory subject devices might be utilized in an adjunctive supportive manner.

3.2. Clinical Problem

Numerous modern surgical procedures require cutting and dissection of tissues. While these procedures can be accomplished with traditional (nonpowered) surgical instruments, they are often performed more efficiently and with less trauma using electrosurgical equipment. Electrosurgical equipment used in most surgical procedures often include an electrosurgical generator, patient return electrodes, and smoke evacuation equipment and their supportive accessory products.

3.3. Treatment Options and Interventions

Therapeutic Alternatives/Treatment Options

Certain gastrointestinal, gynecologic, thoracic, urologic, spinal, and other conditions may require a nonsurgical rather than a surgical approach, in which case surgical devices are not utilized. The absence of any intervention in a “watch and see approach” constitutes a conservative treatment. However, this approach is not an alternative to electrosurgery or to other energy-based surgical systems. There are no non-surgical or pharmaceutical options for dissection and coagulation of tissue, since these tasks by definition require physical manipulation of tissues with sharp instruments and/or heat. Therefore, all of the alternative therapies included in this State-of-the-Art assessment involved use of either traditional surgical dissection (i.e., cold/blunt dissection) or an energy-based system such as monopolar electrosurgery, bipolar electrosurgery, advanced bipolar electrosurgery, or ultrasonic surgery.

3.3.1. Surgical

3.3.1.1. Surgical - Non-energy-based options

Dissection, one of the core tasks required for surgery, refers to the separation of various parts of the body in order to expose or study its anatomical structures. Surgical dissection encompasses both blunt dissections, or the meticulous separation of tissues by the fingers or blunt instruments, and sharp dissection, or the separation of tissue with the sharp edge of a knife, scissors, or scalpel. Non-energy based surgical devices for dissection have been used for millennia, but these instruments are usually too bulky and inappropriately designed to be leveraged in modern laparoscopic procedures. However, they may be used in some minimally invasive procedures, depending on the surgeon's preference and on the availability of manual versus energy-based cutting and hemostatic devices. Additional manual tools such as cautery, forceps, and scissors may be utilized in conjunction with scalpels during surgical dissection.

The "clamp-and-tie" technique for hemostasis was initially standardized in the 19th century, but with several modifications it is still used in current surgical techniques where ligatures, titanium vessel clips or staples are applied. While new tools based on the transmission of electricity and ultrasonic energy have been introduced as hemostatic aids in a variety of surgeries, the traditional "clamp-and-tie" technique remains a state of the art approach for controlling intraoperative and postoperative bleeding (Binsaleh, 2011; Garas et al., 2013). In addition, cautery can be used manually to remove a part of the body or to seal a blood vessel using heat. Topical hemostatic agents provide another medicinal technique for promoting coagulation during surgery. Topicals encompass physical agents that facilitate hemostasis through a passive process as well as biologically active agents that increase coagulation at the bleeding site (Galanakis et al., 2011). The alternative therapies included in this report did not include topical hemostatic agents.

3.3.1.2. Surgical - Energy based options

In contemporary clinical settings energy-based surgical systems are used to facilitate the application of energy in the surgical or endoscopic field where they produce clinical effects such as cutting, coagulation, or desiccation of tissue, or fulguration for the destruction or manipulation of the tissue (Sankaranarayanan et al., 2013; Schwaitzberg, 2012). These systems encompass devices that utilize technologically sophisticated energy sources such as high frequency (radiofrequency) electrical energy and ultrasonic energy for a wide range of procedures, including minimally invasive surgery (MIS). Energy-based modalities used in laparoscopic procedures and other forms of MIS include monopolar electrosurgery, bipolar electrosurgery, advanced bipolar electrosurgery, ultrasonic energy, laser devices, argon beam devices and hybrid devices that combine electrosurgical and ultrasonic energies. These devices sometimes incorporate additional functions such as tissue sealing, temperature feedback regulation, and simultaneous tissue cutting and hemostasis (Grochola and Vonlanthen, 2016). Some general benefits and risks of these energy-based modalities are detailed in Table 3.

Energy systems such as electrosurgery are used in clinical practice in compliance with Clinical Practice Guidelines such as the Dutch Health Care's multidisciplinary evidence-based guideline for minimally invasive surgery and electrosurgical techniques (la Chapelle et al., 2012), AORN's Recommended Practices for Electrosurgery (AORN, 2012; Spruce and Braswell, 2012), AST Standards of Practice for Use of Electrosurgery (AST, 2012), and Guideline Implementation: Surgical Smoke Safety (Fencl, 2017).

Table 2: Benefits/Advantages and Disadvantages/Risks of Energy-based Systems

(Law et al., 2014; Sankaranarayanan et al., 2013; Vilos and Rajakumar, 2013)

Energy System	Benefits/Advantages	Disadvantages	Risks
Monopolar Electrosurgery	Varied tissue effects – e.g., desiccation, vaporization, fulguration, coaptation Parameters are under surgeon's control Minimal smoke production or carbonization Superior dissecting capabilities according to some surgeons Relatively low cost	Higher voltage requirement to achieve desired tissue effect Risk for thermal injury Smoke plume Technique requires extensive knowledge, understanding, and vigilance to avoid inducing unintentional thermal injury	More pronounced lateral thermal spread than vaporization or fulguration Potential stray current injuries due to capacitive coupling, insulation coupling, and direct coupling Laparoscopic electrosurgical injuries: reported rate of 1 to 5 per 1000 operations
Bipolar Electrosurgery	Decreased risk of stray current injury than with monopolar electrosurgery Ability to seal larger vessels Lower voltage requirement than monopolar electrosurgery to achieve desired tissue effect More even distribution of thermal effect that might reduce risk of lateral thermal spread Reduced risk of stray current injury from capacitive coupling Shorter dissection time High success rates Better sealing quality Less blood loss Fewer conversion rates More cost effective than monopolar electrosurgery	Decreased ability to modify operational parameters compared with monopolar electrosurgery Lack of versatility of tissue effects (e.g., no vaporization or fulguration) Requires mechanical cutting blade because bipolar electrodes cannot cut tissue Smoke plume Risk for thermal injury	Lateral thermal spread Electrode adherence to tissues Disengagement of instrument tips may cause tissue trauma or tearing of blood vessels

Energy System	Benefits/Advantages	Disadvantages	Risks
Advanced Bipolar Electrosurgery	Thermal effects may be minimized with advanced bipolar Seal vessels up to 7 mm in diameter Lowest possible power setting can be used utilized to achieve desired tissue effect Advanced Bipolar electrosurgery systems alert the operator via an audio signal when desired tissue effect has been achieved, minimizing Optimal thermal and mechanical properties to seal the tissues	Instruments need to be changed to transect the desiccated tissue Smoke plume Risk for thermal injury Requires mechanical cutting blade because bipolar electrodes cannot cut tissue	Lateral thermal spread risk still exists (potentially associated with prolonged device activation) Electrode adherence to tissues Disengagement of instrument tips may cause tissue trauma or tearing of blood vessels
Ultrasonic Surgery	No need for electric current to pass through the tissues Provides hemostasis and cuts tissues Vessel-sealing tissue effects are comparable to those of advanced bipolar electrosurgery Can perform desiccation and coagulation with resultant coaptation at temperatures lower than 100°C Harmonic ACE+7 seals vessels up to 7-mm diameter (beyond 5-mm limit associated with all the other ultrasonic devices) Overall dissection time may be shorter after initial learning curve Less instrument traffic due to the combined vessel-sealing and tissue cutting functionality, less tissue and charring, reduced lateral thermal spread	More expensive than conventional electrosurgical devices Instrument tip temperatures higher than with advanced bipolar devices Risk for thermal injury Dissection capability of some ultrasonic devices is more limited compared to monopolar scissors or conventional bipolar forceps Slower coagulation compared to electrosurgery; can coagulate only while cutting Changing frequency or impedance of surgical system may be due to blade fatigue, temperature elevation, excessive applied pressure, or improper use Some ultrasonic devices are less efficient than other advanced energy devices in sealing medium to large sized blood vessels Higher average temperatures that are not reliable in sealing vessels larger than 3mm	Lateral thermal spread risk still exists Plume aerosol produced consisting of tissue, blood, and blood products can adversely affect patients and OR personnel. Heat generated from use can cause tissue burning.

Energy System	Benefits/Advantages	Disadvantages	Risks
	Less smoke plume (Harmonic Scalpel)	Sealing efficiency is more technique dependent than advanced bipolar instrumentation	
Argon Beam Coagulation	Enhances vessel sealing capabilities of monopolar electrosurgery Argon jet blows away blood and debris from the surgical field. Suitable for minor capillary bleeding after dissection Beneficial for procedures involving major blood loss Oncological indications (e.g., advanced tumor resection) Non-oncological indications (endoscopic bleeding control in the gastrointestinal tract and general surgery)	Cannot be used for tissue dissection Inappropriate for control of significant bleeding or larger vessels Risk for thermal injury	Insolubility of argon gas results in risk for serious complications (e.g., potentially fatal argon gas embolism, pneumothorax) Risks for complications of pseudoaneurysm formation and hemobilia in laparoscopic cholecystectomy May interference with surgical equipment Higher risk for death from complications than other energized surgical methods (except for laser surgery coagulation)
Laser Energy Surgery	Used largely in surgical procedures to treat benign prostatic hyperplasia (BPH) and gynecological, eye, and dermatological condition Reduces the risk of infection, promoting healing	Expensive Requires specialized training and skill Poor sealing capability Higher risk for causing damage away from the operative site Risk for thermal injury	Risks for pregnancy Contra-indications for the use of photosensitizing drug Higher risk for death from complications than other energized surgical methods (except for argon beam coagulation) Laparoscopic cholecystectomy pseudoaneurysm formation and hemobilia in laparoscopic cholecystectomy Risk for hemorrhage

3.3.1.3. Electrosurgery

Overview

Electrosurgery is an umbrella term encompassing multiple surgical modalities that use a high-frequency (radiofrequency) electric current of alternating polarity. More than 80% of surgical procedures performed in the current clinical environment utilize advanced devices such as electrosurgical instruments (Meeuwsen et al., 2017).

Electrosurgical instruments are precisely crafted to allow skilled surgeons to perform a variety of techniques during surgical procedures that involve tissue grasping, tissue cutting (incision, dissection, resection) and coagulation to achieve hemostasis (sealing of blood vessels). Electrosurgical devices play a pivotal role in MIS such as laparoscopic procedures, including appendectomy, cholecystectomy, colorectal procedures, and various other gastrointestinal operations, as well as hepatic, gynecologic, thoracic, urologic, and spinal procedures. MIS is performed with the use of various instruments, often custom designed, that have been scaled down in size or in some cases miniaturized for ease of insertion into the surgical field. Electrosurgical instruments are also increasingly used in traditional or open, operations as an alternative to the conventional dissection and hemostatic techniques. The core equipment in electrosurgery, as performed in clinical practice, is an electrosurgical unit (ESU) consisting of a generator and hand piece with one or multiple electrodes. The operator controls the unit with the use of a hand- or foot-controlled pencil or switch (Cordero, 2015). High-frequency electrical current, generated from the flow of electrons, is applied to living tissue in order to perform surgical cutting or to control bleeding (Law et al., 2014).

Categories of Electrosurgical Devices

Electrosurgical instruments utilized in both MIS and traditional open operations fall into three main categories: monopolar, traditional bipolar, and advanced bipolar. In addition, a small number of hybrid devices are currently commercially available that combine two or more distinct types of RF energy, integrate RF energy with ultrasonic energy, offer multifunctional clinical applications, or provide both multiple energy platforms and multifunctional features within the same instrument (Law et al., 2014; Obonna and Mishra, 2014).

RF electrosurgery is now widely used as an effective method of cutting and, to some extent, of achieving hemostasis, at least in smaller blood vessels, during a broad array of surgical procedures (Munro, 2012). In contrast to other modes of electrosurgery, monopolar electrosurgical devices are typically used in clinical settings for achieving hemostasis in vessels smaller than 2mm in diameter (Ferreira, 2015). Bipolar electrosurgical instruments offer some safety advantages when used for the processes of coagulation and desiccation, but in general these devices provide limited benefit for cutting or vaporization (Munro, 2012).

ESUs utilize three different waveforms known as Cut, Coag, and Blend output settings to achieve different tissue effects (Alkatout et al., 2012). The “cut” setting delivers an unmodulated, continuous current, whereas the “coag” setting delivers a modulated, interrupted current. Per Ohm’s law, at the same power settings, an interrupted waveform has a higher voltage but a lower current than a continuous waveform. Continuous waveform current uses lower-energy electrons than those used in interrupted waveform current, thereby making continuous waveform a safer waveform option for most laparoscopic applications. Various “blend” settings can be adjusted on most ESUs to alter the proportion of time in which the current flow is interrupted (Law et al., 2014). All modern ESUs are designed to provide power in either monopolar or bipolar configurations (Vilos and Rajakumar, 2013).

3.3.2. Ultrasonic Energy Devices

Background

Ultrasonic shears or scissors utilize sound waves characterized by vibrations with a high frequency greater than 20,000 Hz, falling beyond the audible spectrum of the human ear. These devices are often referred to by the generic name (i.e., proprietary eponym) of Harmonic Scalpel, the leading trademarked product among ultrasonic energy shears and scissors. The Harmonic Scalpel delivers a form of energy that simultaneously divides and coagulates tissue using a titanium blade vibrating at 55,000 Hz while preventing bleeding. The resulting temperature (ranging from 50 to 100°C) creates denatured protein coagulum (Binsaleh, 2011). This device differs from electrosurgical tools by not requiring conduction through tissues, but it does demand contact with tissues (Baggish, 2012). In MIS, ultrasonic energy is used in the operation of surgical devices designed mainly to provide vessel sealing. Ultrasonic devices are based only on mechanical action without passage of any current affecting the patient, thereby decreasing the risk of nerve damage.

Advantages and Benefits of Ultrasonic Shears

Modern ultrasonic technology reportedly allows for more uniform hemostasis as well as increased functionality and improved efficiency when compared to other energized surgical instruments during procedures. Ultrasonic surgical devices generate physiologic burst pressure for sealing blood vessels that is comparable to the burst pressure used in earlier versions of surgical clips or ligatures. Ultrasonic energy systems are associated with minimal lateral thermal damage and minimal smoke (mist or vapor) (Broughton et al., 2013). The Ethicon Harmonic Scalpel and related devices in this product family are multifunctional ultrasonic devices used to perform coagulation and transection of tissue, vessel sealing, and fluid evacuation.

Clinical evidence shows that the Harmonic Scalpel seals vessels ≤ 5mm with decreased operating time and intraoperative blood loss than observed with other energy surgical devices. The Harmonic ACE+7, another product in this line, has received FDA clearance for sealing of vessels up to 7mm. The benefits of Harmonic Scalpel instruments include minimal heat production, less charring and plume, and less thermal injury to surrounding tissues compared with bipolar energy devices (Alkatout et al., 2012; Entezari et al., 2007). Additional reported advantages of these devices include less tissue necrosis, less instrument traffic (required to perform coagulating and cutting), absence of electrical current and therefore no electrical current passage to the patient, and no foreign material left behind after the procedure (Entezari et al., 2007). Harmonic Scalpel shearing instruments allow for a tension free application and in some studies have demonstrated better healing compared with electrosurgery and lasers for certain applications, as well as improved visualization (Alkatout et al., 2012).

Some evidence demonstrates that ultrasonic shears, particularly Harmonic Scalpel devices, are more effective than other advanced energized surgical tools for cutting through thicker tissue, generating safer as well as less smoke, and potentially offering greater precision. Furthermore, lower rates of tissue damage and wound complications have been reported for ultrasonic surgical energy when compared with electrocautery (standard electrosurgery) (Sinha, 2014). In kidney surgical procedures, ultrasonic shears are advantageous for tumor excision without vascular occlusion, thereby reducing the possibility of renal ischemic damage (Binsaleh, 2011).

3.3.3. Guidelines on the use of Energy-based surgical instruments

The use of energy-generating equipment, including electrosurgical units (ESUs), lasers, and argon beam coagulators used for tissue dissection and coagulation poses a risk for unintended injury if these items are used incorrectly. Some guidelines, including the Association of peri Operative Registered Nurses (AORN) “Guideline for safe use of energy-generating devices” provide guidance on the use and maintenance of devices that deliver energy in the forms of radiofrequency waves, ultrasound waves, or lasers (Eder, 2017). Electrosurgical equipment used in perioperative settings potentially can cause thermal injuries (including burns to surgical and nursing staff), interfere with implanted devices, ignite fires and generate detrimental plume that can adversely affect both patients and perioperative personnel.

Therefore, current evidence-based guidelines on energy-based devices address precautions to mitigate the risk associated with electrosurgical units, particularly during minimally invasive surgery; fire safety practices the safe use of these instruments in patients who have an implanted electronic device; and actions to take following an injury or equipment failure during the use of an energy-generating device (Eder, 2017).Published guidelines for energy-based devices are limited and primarily include publications issued by AORN on the use of energy-generating devices for Perioperative RNs. These guidelines are applicable to a wide range of health care practitioners and surgical technicians who work in the presence of a large number of energy-generating devices used in the OR. However, only some of the guidelines identified in the current literature are based on systematic literature reviews as described below (see Table 3).

Table 3: Examples of Current Guidelines for Energy-based Surgical Devices

Tonsillectomy using ultrasonic scalpel Interventional procedures guidance [IPG178] Published date: June 2006	**AORN Recommended Practices for Electrosurgery**	**AST Standards of Practice for Use of Electrosurgery (AST, 2012).**
Published in June 2006	Effective July 1, 2009. Originally published March 1985, *AORN Journal.*	2012
Makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund the procedure.	These recommended practices provide guidance to perioperative nurses in the use and care of electrosurgical equipment, including high frequency, ultrasound, and argon beam modalities.	To support healthcare facilities (HCF) and reinforce best practices related to electrosurgery safety in the perioperative setting. The purpose of the Standards is to provide an outline that surgical team members can use to develop and implement policies and procedures for electrosurgery safety. The Standards are presented with the understanding that it is the responsibility of the HCF to develop, approve and establish policies and procedures for electrosurgery safety, per established HCF protocols
The medical literature was searched to identify studies and reviews relevant to ultrasonic scalpel for tonsillectomy. Searches were conducted via the following databases, covering the period from their commencement to August 2005 MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.	These recommended practices address all of these technologies and do not endorse any specific product.	Measurable criteria include educational standards as established by the Core Curriculum for Surgical Technology.
Narrative literature review with expert conclusions based on current evidence on the safety and efficacy of tonsillectomy using ultrasonic scalpel appears adequate to support the use of this technique provided that normal arrangements are in place for consent, audit and clinical governance.	These recommended represent what is believed to be an optimal level of practice.	The publication consists of 14 Standards of Practice researched and written by the Association of Surgical technologists (AST) Education and Professional Standards Committee.

Tonsillectomy using ultrasonic scalpel Interventional procedures guidance [IPG178] Published date: June 2006	**AORN Recommended Practices for Electrosurgery**	**AST Standards of Practice for Use of Electrosurgery (AST, 2012).**
The Specialist Advisers did not have any particular concerns about the efficacy of this procedure but noted that the evidence base was still small and that a number of the studies had methodological limitations. The Specialist Advisers stated that the safety is much the same as for any other method of tonsillectomy, however it appeared that there is a slight increase in postoperative hemorrhage compared with cold steel dissection.	Electrical Surgical Units (ESUs) and accessories should be selected based on safety features that minimize patient and personnel injury. the risk of alternate site injuries. the risk of insulation failure and capacitive coupling injuries, the risk of unintentional activation.	"CSTs are knowledgeable of the risks, patient and surgical personnel hazards and safety principles associated with the use of ESU and accessory items."
-Nine comparative studies, including three randomized between-patient comparisons and three within-patient comparisons. -Six studies assessed pain following tonsillectomy using ultrasonic scalpel, cold steel dissection or diathermy. Return to normal diet or appetite was assessed in four studies.	66 References were cited; no further information provided.	Risk factors identified with the use of electrosurgery included fire, patient burns, surgical personnel injuries, and biological hazards, such as plume, which are addressed by safety standards.

3.4. Maturity of Technology of the Target Therapy

Energy-based systems involving monopolar electrosurgery, bipolar electrosurgery, advanced bipolar electrosurgery, ultrasonic, and hybrid configurations of two or more of these systems have become the standard of care in cutting, dissection, coagulation, and in some cases, additional functions required for MIS in diverse anatomical regions. Energy-based instruments are commonly used to perform various gastrointestinal as well as hepatic, gynecologic, thoracic, urologic, and spinal procedures.

Historically, the origins of electrosurgery can be traced to the first use of electrocautery in the early 1800s. The predecessor of the contemporary electrosurgical devices was invented in the 1920s and used therapeutically until a smaller unit was manufactured in the 1960s. In current clinical practice, electrosurgery, including electrosurgical instrumentation, plays a critical role in laparoscopic surgery, utilizing various devices inserted into the surgical field, sometimes through a trocar sleeve. These instruments are used routinely in surgical operations, both traditional open and minimally invasive, to provide essential functions of tissue cutting, dissection, and coagulation (Rozner and Jones, 2012).

Laparoscopic surgery often requires drainage of fluids and irrigation of wound surfaces in order to render them clean and sufficiently visible to the surgeon (Ferreira, 2015). In traditional electrosurgery, an irrigator is used to clear debris or blood from bleeding, whereas a suction pump or central vacuum supply system may be employed to remove irrigation fluid or intraperitoneal air and smoke. Alternatively, a large suction-irrigation probe may be utilized to remove blood clots in cases of abrupt bleeding. Only a limited number of electrosurgical combined suction-irrigation devices are currently on the market that simultaneously perform versatile functions, including blunt dissection, coagulation, irrigation, and fluid suction (e.g., the Endopath Probe Plus II and Megadyne All-in-One, two subject devices of this SOA Report, and the GORDTS/CAMPO coagulating suction and irrigation cannula by Karl Storz).

Since its inception and widespread use almost a century ago, energy-based surgery has been improving steadily with the myriad of surgical techniques and variants with a focus on performing the essential functions of tissue cutting, dissection, and coagulation. This is especially needed in the laparoscopic field where non-energy-based surgical instruments alone prove to be difficult to use in dissection. However, the risks inherent in the nature of the technology used continue to persist even into the current era, such as electrothermal injury due to accidental direct application of the device. These risks have since been mitigated steadily through improved technological warning systems such as audio signaling, improved design, temperature control for electrosurgical generators, and the development of new variants of electrosurgery that use the minimum amount of power and hence minimize patient injury to perform its intended effect. Indeed, advanced versions of these electrosurgical instruments are already being developed and with some being already in use to answer the shortcomings of the current technology (Law et al., 2014).

3.5. Summary of Safety and Performance within the SOA

The core equipment for energy-based surgery includes an electrosurgical generator, patient return electrodes, and smoke evacuation devices. Each of these families of Class IIa and IIb energy-based electrosurgical devices require supportive adjunct Class I devices to allow proper connections and operation within the surgical suite. These Class I adjunctive accessory devices are the subject of this CER. This State-of-the Art discussion has demonstrated that energy-based electrosurgical devices are within current State-of-the Art; therefore, the adjunctive Class I accessory devices required for their support within the surgical suite are also within current State-of-the Art.

4. SUBJECT DEVICE DESCRIPTION

4.1. Design and Specifications

For product codes 0825, M2K01, M2K02, M2K03, M2K04, M2K05, M2K06, M2K07, M2K08, M2K09, PKIT001 - Refer to Technical Documents RA-TECH-0003 and Device Master Record ENG-DMR-005 Rev 010.

For product codes 0075, 1300SJ, 1300U, 1400JJ, 1450J - Refer to Technical Documents RA-TECH-0007 and Device Master Record ENG-DMR-008 Rev 009.

For product codes 2140J, 2145J, 2150J, 2151J, 2211J, 2220J - Refer to Technical Documents RA-TECH-0002 and Device Master Record ENG-DMR-012 Rev 008.

4.2. Associated Devices and Accessories Not Included in CER Scope

Accessories used with the Megadyne Class I Accessory Products but not in scope of this CER are equipment and devices needed to perform an electrosurgical procedure and may include the Megadyne products following:

- Megadyne Reusable Patient Return Electrodes Mega 2000 (product code 0800) and Mega Soft (product codes 0830, 0835, 0840, 0845, and 0846).

0830

0835

0840

0845

0846

- Megadyne Mega Power Generator (product code 1000)

- Megadyne MegaVac Smoke Evacuator (product code 2200J)

4.3. Materials and Biocompatibility

The Megadyne Class I Accessory Products are used in such a way that there is no patient contact with any part of the in scope products. They contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. Therefore, biocompatibility testing is not required for this device.

4.4. Intended Purpose

The Megadyne Class I Accessory Products are intended to be used adjunctively as accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER.

4.5. Clinical Claims

There are no clinical claims made for the Megadyne Class I Accessory Products. The only nonclinical claim made for the device family is that they meet the intended purpose as adjunctive accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER. No additional clinical claims are made for the subject devices.

4.6. Indications

Not applicable. The products are designed to be used adjunctively as accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER. They have no diagnostic or therapeutic indications or contraindications independent of their intended adjunctive use.

4.7. Contraindications

Not applicable. The products are designed to be used adjunctively as accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER. They have no diagnostic or therapeutic indications or contraindications independent of their intended adjunctive use.

4.8. Adverse Events / Side Effects

Not applicable. The products are designed to be used adjunctively as accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER. They have no diagnostic or therapeutic indications or contraindications independent of their intended adjunctive use. Therefore, no adverse events or side effects are anticipated for these class I low risk device accessories.

4.9. Warnings and Precautions

The following warnings and precautions are listed the IFUs:

Reusable Foot Control Cable, 3 m (10 ft) - Product Code 0075 (IFU: 3000051-01 Rev 003)

WARNINGS:

- When not in use, store active electrodes in an electrically insulated container.
- Electrosurgical tips that are activated or hot from use can cause fire. Do not place them near or in contact with flammable materials and substances (e.g. drapes, flammable gases, endotracheal tubes, etc.)
- Use the lowest possible power setting to achieve the desired effect.
- For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area (e.g. circumcisions), the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Do not modify this device.
- Do not immerse or soak the cable in cleaning/sterilization solutions.
- Electrosurgical cables should be positioned to minimize contact with the patient and avoid contact with other leads to avoid adversely influencing the operation of other electronic equipment.
- Activate electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.

CAUTIONS:

- Refer to the generator manufacturer's operating manual for proper usage of electrosurgical equipment.
- Rx only Federal (USA) law restricts this device to sale by or on the order of a physician.

ULPA Filter with Fluid Trap - Product Code 2211J (IFU: 3000190-01 Rev 003)

CAUTIONS:

- Do not use ULPA Filter with Fluid Trap as primary fluid collector. This will shorten the filter's life.
- Install cap prior to disposal to prevent spillage.
- Do not clean or otherwise sterilize. Doing so will diminish its effectivness.
- Rx only Federal (USA) law restricts this device to sale by or on the order of a physician.

Charcoal Filter (MEGA VAC™) – Product Code 2220J (IFU: 3000191-01 Rev 002)

- Do not clean or otherwise sterilize. Doing so may result in damage.
- If device is damaged, discard and do not use.
- Rx only Federal (USA) law restricts this device to sale by or on the order of a physician.

Replacement Pigtail Cable - Product Code M2K07 (IFU: 3000124-01 REV 004)

CAUTIONS:

- Electrosurgical cables should be positioned to minimize contact with the patient and avoid contact with other leads to avoid adversely influencing the operation of other electrical equipment.
- Rx only Federal (USA) law restricts this device to sale by or on the order of a physician.

4.10. Device Lifetime / Duration of Use

MEGA 2000™ Sheath – Product Code 0825

The Mega 2000 Sheath is used with the Mega 2000 Reusable Patient Return Electrode only. The sheath is replaced on a daily basis; it is intended to be reused several times per day. The Mega 2000 Reusable Patient Return Electrode Instructions for Use (IFU 3000046-03) state the sheath is to be inspected before and after each use and that it is to be replaced at least once per day or replaced if damaged or contaminated with bodily fluids.

Mega Soft Reusable DetachaCable™ Cords – Product Codes M2K01, M2K02, M2K03, M2K04, M2K05, M2K06, M2K07, M2K08, M2K09

The Mega Soft and Mega Soft Dual and Pediatric Patient Return Electrodes are used intraoperatively for the duration of a procedure and can be reused per instructions in their IFUs (3000068-01 and 3000141-01). The devices are intended to be used as a 24-month patient return electrode for all patients. The Mega Soft 0830 has a single cord that connects to one generator. The Mega Soft Dual 0835 has two cords that can connect to one or two generators.

Mega Power Reusable Foot Control Cable (Product Code 0075), Mega Cart and Mega Cart with Top Shelf (Product Codes 1300U and 1300SJ), Monopolar Footswitch (Product Code 1400J), and Bipolar Footswitch –(Product Code 1450J)

These accessories are reusable capital equipment. The device lifetime is defined as a device service life. That is, these accessory devices can be used until they reach the end of their service life. Refer to Technical Documents RA-TECH-0007 and Device Master Record ENG-DMR-008 Rev 009.

MegaVac Accessories – Product Codes 2140J, 2145J, 2150J, 2151J, 2211J, and 2220J

The MegaVac accessory products are designed for one time use and are disposed after the electrosurgical procedure.

4.11. Magnetic Resonance Imaging (MRI) Compatibility

Not applicable. The Megadyne Class I Accessory Products are not implantable devices and use within an MRI environment is not anticipated.

4.12. Sterility

The Megadyne Class I Accessory Products are provided non-sterile.

4.13. Principles of Operation

The Megadyne Class I Accessory Products are intended to be used as accessory devices for other Class IIa and IIb devices described in Section 4.2 which are not in scope of this CER. These accessory products are used in accordance with the procedures outline in their respective IFUs for these other Class IIa and IIb devices.

5. EQUIVALENCE

Due to the nature of the subject devices, clinical data is neither appropriate nor required to establish the product is safe and performing as intended. Rather, risk analysis and risk mitigations as confirmed by appropriate bench testing and compliance to applicable standards (Section 6.2) and Post-Market Surveillance data (Section 6.6), demonstrate conformity with all applicable essential requirements (ERs). Therefore, no equivalent comparator is required. Refer to Section 2.3 for complete justification of the clinical evaluation route which is utilizing MDD Annex X 1.1d.

6. DATA SOURCES - IDENTIFICATION AND APPRAISAL (STAGE 1, 2)

6.1. Data Appraisal Plan

Comprehensive methods were utilized to identify and appraise all data sources that are generated and held by Megadyne, Inc. for the subject devices. The appraisal of each data source is described below, with further details in subsequent sections for each data source.

For nonclinical testing (Section 6.2), the test methods/study design were assessed to ensure they were considered representative of the intended use of the subject device and of the treatment population.

Post-market surveillance data (Section 6.6), including complaints and sales, vigilance, CAPA, Escalations, Field Actions, and Alerts; provides valuable information towards the assessment and confirmation of safety for the subject devices and reflects real world usage.

Risk management data (Section 7), including identified clinical risks, benefits, and information provided to the user on residual risks are evaluated in comparison to the other data sources. to determine the acceptability of the known side effects, if any, for these low risk device accessories from PMS and to compute the benefit-risk ratio.

The following matrix in Table 4 identifies the data sources being used to support safety and/or performance of the subject devices to substantiate the identified ERs[1]. Please refer to the ER Checklist in Technical Files RA-TECH-0003, RA-TECH-0007, and RA-TECH-0002 for data supporting all other ERs.

Table 4: Data Source Contribution

Data Source	Performance / Clinical Benefits	Safety/Clinical Risks	Side-Effect Acceptability	Benefit-Risk Profile Acceptability
MDD ERs	3	1	6	1
Nonclinical				
Bench-Top Data	X	X	X	X
Analytical Data	X	X	X	X
Complaints / Sales Data		X	X	X
Vigilance Data (MDVs, FDA-MDRs)		X	X	X
CAPAs, Field Actions, Escalations		X	X	X

6.2. Non-Clinical Data

The design requirements of the Megadyne Class I Accessory Products have been investigated and defined in the specification documents in Technical File RA-TECH-0003, RA-TECH-0007, and RA-TECH-0002. The design verification activities have been confirmed through examination and provision that the design outputs of device design meet the design requirements (design inputs). The design validation activities

[1] The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In order to establish that the subject device is part of the "state of the art" applicable standards and guidance documents and information relating to the medical condition managed with the device and its natural course, benchmark (i.e. equivalent) devices, other devices and medical alternatives available to the target population should be evaluated.

have ensured that finished device design and manufacturing, including packaging and labeling, conforms to defined customer requirements (user and patient needs) to allow the specific intended purpose to be consistently fulfilled. The design validation further evaluated the performance of initial production units, lots, batches, or devices justified to be representative under actual or simulated use conditions. Megadyne, Inc., in accordance with EN ISO 14971, has undertaken all necessary steps to apply standard techniques in designing and manufacturing the subject devices to ensure they are safe and perform as intended. The available non-clinical dataset substantiates the Megadyne Class I Accessory Products in scope of this CER for adjunctive use as accessory devices for other Class IIa and IIb devices described in Section 4.2 (which are not in scope of this CER), and further identifies the residual risks from its design and production as specified in the Data Appraisal Plan Section. The subsequent section summarizes the non-clinical datasets where key design requirements are provided from the Technical Documentation (Table 5).

Table 5: Non-Clinical Data Summary

Reference	Device/Design Input	Test Description	Results	Conclusion
Product Codes: 0825, M2K01, M2K02, M2K03, M2K04, M2K05, M2K06, M2K07, M2K08, M2K09, PKIT001 for use with Megadyne Reusable Patient Return Electrodes				
MKT-CMR-034	The UP/UDP comes in one configuration that includes the ability to connect to the existing M2K-07 cable.	Same corner overmold sub-assembly (6020175-01 rev001) is used for both the Universal pads and the Universal Plus pads. Insertion and extraction testing per test protocol ENG-PRT-314.	No change to the overmold corner assembly or the M2K-07 cable, using the same overmold corner and cables as the Universal pads. Compared BOM on 6020174-01 rev004 – Universal pad drawing to 6020310-01 rev003 – Universal Plus pad drawing for reference use of 6020175-01 rev001 drawing. Same for Dual corner pads, 6020187-01 rev004 – Universal pad drawing to 6020311-01 rev003 – Universal Plus pad drawing for reference to 6020186-01 rev001. No new or additional testing required, ref. test report ENG-RPT-056.	Pass
Megadyne drawing 6020064-01	The insertion force of the M2K-07 into the UP/UDP pad corner overmold is < 20 lb. when inserted at 1 inch/min.	< 20 lbs. when inserted at 1 inch/min. into pad corner per test protocol ENG-PRT-314	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-056.	Pass
Megadyne drawing 6020064-01	The extraction force of the M2K-07 from the UP/UDP pad corner overmold is > 20 lb. when extracted at 1 inch/min.	> 20 lb. when extracted at 1 inch/min. from pad corner per test protocol ENG-PRT-314	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-056.	Pass
IEC 60601-2-2, section 201.15.101.2	The M2K-07 shall be reliably connected to the UP/UDP such that the resistance is 1 ohm or less when tested using at least 1.0 A but not more than 5.0 A from a dc. or mains frequency with a no-load voltage not exceeding 6 V.	Test per test protocol ENG-PRT-233	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-334.	Pass
IEC 60601-2-2 section 201.8.8.3.102 and 201.15.101.4	Mains dielectric withstand, 60 Hz.	Using same material and cables as the Adult Mega Soft so no additional testing needed. Test protocol ENG-PRT-096.	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-302.	Pass
IEC 60601-2-2 section 201.8.8.3.102 and 201.15.101.4	High frequency leakage current and dielectric.	Using same material and cables as the Adult Mega Soft so no additional testing needed. Test protocol ENG-PRT-096.	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-302.	Pass
IEC 60601-2-2, section 201.15.101.3 & Subclause 201.15.101.3	Any contacts on the Mega Soft cables shall not allow the conductive parts to come in contact with the body of the patient when disconnected such that the contact quality monitoring system produces a false	Use standard test finger shown in 60601-1 Edition 3 section 5.9.2.1.	No change to the overmold corner assembly or M2K-07 cable. Using the same overmold corner and cables as the Universal pads. No new or additional testing required, ref. test report ENG-RPT-405.	Pass

Reference	Device/Design Input	Test Description	Results	Conclusion
	indication of proper attachment of the return electrode.			
ASTM D 4169	Package and Ship testing	Per test protocol # 1150369-10	No additional testing need for the new shorted cable. New shorted cable is identical, on the exterior, to the current M2K-07 cable that is shipped without any issues. Testing done on old design is still valid; see Phase II section 2.9 and Phase III section 3.37 in the DHF for information on testing done.	Pass
CMR MKT-CMR-028	PRS 5200: The UMS comes in one configuration that includes the ability to connect to the existing M2K-07 cable.	Insertion and extraction testing per test protocol ENG-PRT-314	Test report 1150232-02	Pass
Megadyne drawing 6020064-01	PRS 5313: The insertion force of the M2K-07 into the UMS pad corner overmold is < 20 lb. when inserted at 1 inch/min.	< 20 lbs. when inserted at 1 inch/min. into pad corner per test protocol ENG-PRT-314 & ENG-PRT-027	Test report 1150231-02 & 1150232-02	Pass
Megadyne drawing 6020064-01	PRS 5314: The extraction force of the M2K-07 from the UMS pad corner overmold is > 20 lb. when extracted at 1 inch/min.	> 20 lb. when extracted at 1 inch/min. from pad corner per test protocol ENG-PRT-314 & ENG-PRT-027	Test report 1150231-02 & 1150232-02	Pass
IEC 60601-2-2, section 201.15.101.2	PRS5403: The M2K-07 shall be reliably connected to the UMS such that the resistance is 1 ohm or less when tested using at least 1.0 A but not more than 5.0 A from a d.c. or mains frequency with a no-load voltage not exceeding 6 V.	Test per test protocol 1150724-10	Test report 1150724-01	Pass
CMR MKT-CMR-028	PRS 5200: The UDMS comes in one configuration that includes the ability to connect to the existing M2K-07 cable.	Insertion and extraction testing per test protocol ENG-PRT-314	Test report 1150232-02. No change in corner overmold design or materials between the UMS and UDMS, no new or additional testing required.	Pass, see Universal DHF section 3.5
Megadyne drawing 6020064-01	PRS 5313: The insertion force of the M2K-07 into the UDMS pad corner overmold is < 20 lb. when inserted at 1 inch/min.	< 20 lbs. when inserted at 1 inch/min. into pad corner per test protocol ENG-PRT-314 & ENG-PRT-027	Test report 1150231-02 & 1150232-02 No change in design or materials between the UMS and UDMS, no new or additional testing required.	Pass, see Universal DHF section 3.5
Megadyne drawing 6020064-01	PRS 5314: The extraction force of the M2K-07 from the UDMS pad corner overmold is > 20 lb. when extracted at 1 inch/min.	> 20 lbf. when extracted at 1 inch/min. from pad corner per test protocol ENG-PRT-314 & ENG-PRT-027	Test report 1150231-02 & 1150232-02 No change in design or materials between the UMS and UDMS, no new or additional testing required.	Pass, see Universal DHF section 3.5
IEC 60601-2-2, section 201.15.101.2	PRS5403: The M2K-07 shall be reliably connected to the UDMS such that the resistance is 1 ohm or less when tested using at least 1.0 A but not more than 5.0 A from a d.c. or mains frequency with a no-load voltage not exceeding 6 V.	Test per test protocol 1150724-10	Test report 1150724-01 No change in design or materials between the UMS and UDMS, no new or additional testing required.	Pass, see Universal DHF section 3.5

Reference	Device/Design Input	Test Description	Results	Conclusion
Megadyne drawing # 6020161-01 & -02	Insertion force of ESU plug into typical ESU.	4 to 9 lbs. when inserted at 1 inch/min. into typical ESU.	Using same mold, material and process as the rest of the M2K family of cables, so no additional testing needed. Reference test report 1150230-01.	Pass
Megadyne drawing # 6020161-01 & -02	Extraction force of ESU plug from typical ESU.	4 to 8 lbs. when extracted at 1 inch/min. from typical ESU.	Using same mold, material and process as the rest of the M2K family of cables, so no additional testing needed. Reference test report 1150230-01.	Pass
DMR # ENG-DMR-005	ESU plug life cycling.	2200 ideal insertion and withdrawal cycles without becoming so loose that it will fall out of the ESU under its own weight. See protocol # X1150147-01 rev 03.	Using same mold, material and process as the rest of the M2K family of cables so no additional testing is needed. See test report # X1150147-10.	Pass
IEC 60601-2-2 edition 4 (section 19.3.101)	High frequency leakage through neutral electrodes	HF leakage through Mega Soft family of return electrodes to not increase by more than 5% over current levels with standard M2K cables. See protocol # 1150474-10	See test report # 1150474-01	Pass
MKT-CMR-034	The UP/UDP can be repaired using the same repair kit currently offered (PKIT001).	Repair 3 cuts per IFU 3000072-01 using repair kit REF # PKIT001. Ref. X1150066-10 (only exists as hard copy in DHF).	Using same materials and construction as all of the other Mega Soft pads so the ability to use the repair kit to repair damage to outer surface of pad is the same. No new or additional testing required, ref. test report ENG-RPT-407 and ENG-RPT-040	Pass
CMR MKT-CMR-028	PRS 5311: The UMS can be repaired using the same repair kit currently offered (PKIT001).	Repair 3 cuts per IFU 3000072-01 using repair kit REF # PKIT001.	Test report ENG-RPT-407	Pass
CMR MKT-CMR-028	PRS 5311: The UDMS can be repaired using the same repair kit currently offered (PKIT001).	Repair 3 cuts per IFU 3000072-01 using repair kit REF # PKIT001.	Test report ENG-RPT-407 No change in design or materials between the UMS and UDMS, no new or additional testing required.	Pass, see Universal DHF section 3.5
Product Codes: 0075, 1300SJ, 1300U, 1400JJ, 1450J for use with Megadyne Mega Power Generator				
ENG-PRT-147 ENG-RPT-227	0075 Reusable Foot Control Cable	New Vendor Qual 0075. Design/Sterilization	NA	Pass
ENG-PRT-096, ENG-PRT-147 ENG-RPT-303	0075 Reusable Foot Control Cable	Test Report IEC 60601-2-2 5th Ed Leakage HF and Mains 0075	NA	Pass
ENG-PRT-118 ENG-RPT-193	Footswitch Cables 1400	Test Report Mechanical Testing of Footswitch Cables 1400/Design	NA	Pass
ENG-PRT-158 ENG-RPT-240	1450 Footswitch Cables	Test Report Mechanical Testing of 1450 Footswitch Cables/Design	NA	Pass
Product Codes: 2140J, 2145J, 2150J, 2151J, 2211J, 2220J For use with Megadyne MegaVac Smoke Evacuator				

Reference	Device/Design Input	Test Description	Results	Conclusion
ENG-RPT-556 Rev 001	REPORT, FILTER FIT COMPATIBILITY TEST	This report summarizes the filter compatibility testing of C and EC smoke evacuation connectors (part numbers 2150 and 2155). Testing was conducted per protocol XENGPRT-438, with deviations noted in this report.	The C Connectors (2150) and EC Connectors (2155) passed the testing per protocol XENG-PRT-438 for determining connector compatibility for the filters/fluid traps listed in Table 1. Both a Pass/Fail pull test in which the convoluted tubing breaks/extends prior to connector removal, as well as a Pass/Fail visual inspection were used to determine compatibility. The EC Connector (2155) failed either the pull test and/or visual test per protocol XENGPRT-438 for the Medtronic RapidVac ValleyLab filter and Stryker Neptune tube only configuration, listed in Table 2. The EC connector was not designed to fit either of these filters. Therefore, it is still determined that both the C and EC connectors are compatible with all intended filters at the time of original design. The C and EC connectors are used in several smoke evacuation pencils and accessories. The testing performed here deems each connector compatible with specified filters as summarized in Table 1 (of the report). This compatibility extends to smoke evacuation products beyond the ZIP PEN to which this testing was performed, if the same connector is used with the same smoke evacuation accessory. This procedure may be used in determining compatibility of future smoke evacuation connectors and future smoke evacuation systems as they become available. Appendix B outlines specific filters used in testing. Note that competitive smoke evacuation systems may change filter port designs, which in the future will require further testing should the design change the fit of the connector.	Pass with deviations explained.
ENG-RPT-558	Product Specification Verification Test Report II, Zip Pen	The purpose of this test protocol is to document conformance to requirements of customer and marketing (MKT-CMR-029), usability (MKT-US-002) and product specification (ENG-PS-007) that are not verified under other protocols.	This testing demonstrates that the Zip Pen meets requirements per ENG-PRT-451. Results included testing of the ULPA Filter Attachment including: • 2211 ULPA Filter Attachment: One sample of 2211 and 2140 were tested per the protocol. The requirement per the protocol was met. • 2211 ULPA Filter Efficiency: Documentation is provided, meeting the requirement of the protocol.	Pass

6.3. Pre-Market Clinical Investigations

Per MDD Annex X, 1.1d, demonstration of conformity with the ERs based on clinical data is not deemed appropriate for the Megadyne Class I Accessory Products in scope of this CER. The body of non-clinical evidence was used to demonstrate conformity with all applicable ERs and support the safety and performance of the cable subject devices, and also includes non-clinical, risk management output and PMS data. Clinical data is neither applicable nor appropriate or required for these low risk EU Class I device accessories. As such, no pre-market clinical investigations were conducted. The design of all subject devices was fully tested prior to CE-mark. Bench testing was conducted and was determined to be in compliance with all predefined specifications and applicable standards.

6.4. Ongoing or Completed Post-Market Clinical Follow-Up (PMCF)

Per MDD Annex X, 1.1d, demonstration of conformity with the ERs based on clinical data is not deemed appropriate for the Megadyne Class I Accessory Products in scope of this CER. The body of non-clinical evidence was used to demonstrate conformity with all applicable ERs and support the safety and performance of the cable subject devices, and also includes non-clinical, risk management output and PMS data. Clinical data is neither applicable nor appropriate or required for these low risk EU Class I device accessories. As such, no pre-market clinical investigations were conducted. The design of all subject devices was fully tested prior to CE-mark. Bench testing was conducted and was determined to be in compliance with all predefined specifications and applicable standards.

6.5. Systematic Literature Review Methods (Literature Protocol)

Per MDD Annex X, 1.1d, demonstration of conformity with the ERs based on clinical data is not deemed appropriate for the Megadyne Class I Accessory Products in scope of this CER. The body of non-clinical evidence was used to demonstrate conformity with all applicable ERs and support the safety and performance of the cable subject devices, and also includes non-clinical, risk management output and PMS data. Clinical data is neither applicable nor appropriate or required for these low risk EU Class I device accessories. As such, no pre-market clinical investigations were conducted. The design of all subject devices was fully tested prior to CE-mark. Bench testing was conducted and was determined to be in compliance with all predefined specifications and applicable standards.

6.6. Post-Market Experience and Surveillance (PMS)

Post Market Surveillance (PMS) process for the subject device is conducted under PR-0000385, Franchise Procedure for Post Market Surveillance Plans and Reports to monitor the performance and safety of the Megadyne, Inc. subject devices. In accordance with this procedure, the methods should obtain relevant and new production and post-production information to evaluate any potential early warning signs of design and quality problems, emerging issues or safety signals, and to assign action items as necessary throughout the lifetime of the medical device. The PMS for the Megadyne Class I Accessory Products includes internal, external, and market-based sources of active data analysis as defined in the PMS Plan(s) (Table 6). PMS data has been provided from 01 November 2014 through 31 December 2018 as extracted from the PMS Reports (Table 6).

Table 6: Megadyne Class I Accessory Products PMS Plan and Report Overview

PMS Plan and Report	Report Title	Report Review Period and Conclusions
Plan # RA-REC-018 RE V 001 Report # RA-REC-019 REV 001	POST MARKET SURVEILLANCE REPORT (PMSR) FOR MEGA POWER ELECTROSURGICAL GENERATOR ACCESSORIES, SMOKE EVACUATION ACCESSORIES, AND REUSABLE ELECTRODE ACCESSORIES	01 November 2014 to 31 December 2018 Report Conclusion: There were no adverse trends or signals that could contribute to the efficacy of the Megadyne Class I Accessories product family. The periodic data review will continue as per the PMS procedures. The current PMS plan RA-REC-018 is deemed acceptable.

6.6.1. Scope of PMS Analysis

The scope of the PMS report analysis includes all the product codes within scope of this CER discussed in Table 1 is Section 2.2. The scope of the PMS analysis also includes 2 products codes (1350 and 2155) that have been discontinued and replaced by product codes within the scope of this PMS analysis.

6.6.2. Complaint and Vigilance Data

There are no perceived issues with data streams for this report. Data was pulled from EasyTrak and ECM complaint system. The supporting data is in Appendix I Megadyne Class I Accessories Data Workbook. Complaint data was only available back to November 2014 but remaining quality data was gathered for the entire 5-year period (back to December 2013 as applicable). Complaint data includes 4 years' worth of information. CAPAs, Escalations/Field Actions, Alerts and MAUDE (as applicable) includes 5 years' worth of data. All other data inputs include data only for the specific current time period.

Reactive PMS monitoring was performed by analyzing complaint data and data from other quality system data sources at a granular level. Data reported from November 2014-December 2018 was extracted from the applicable complaint database(s) and other various quality system data sources and analyzed using statistical summaries and critical analyses.

Complaint data (including coding) is reflective of the data in the complaint system at a particular point in time. The data captured in this report is current as of March 8, 2019, including open complaints still within investigation. Complaint data is a dynamic attribute that is updated real time per Complaint Handling procedures and this data, including Product Experience and Analysis Codes, may be updated as additional information is received and processed.

NOTE: Non-complaints, complaints alleging Shipping or Data Entry Errors, and complaints that deemed to be concomitant are not included in the scope of this analysis.

6.6.2.1. Overall Complaints/ Sales Data

6.6.2.1.1. Mega Power Generator Accessories

There were 61 complaint events received from November 2014-December 2018 reporting 61 issues with an overall complaint rate of 0.4342%. Figure 1 and Table 7 present the total number of complaints, sales,

and the complaint rate for the PMS Review period. The complaint counts captured in this graph reflect the total product quantity involved in the unique reported events.

Figure 1: Mega Power Electrosurgical Generator Accessories Complaints and Rate

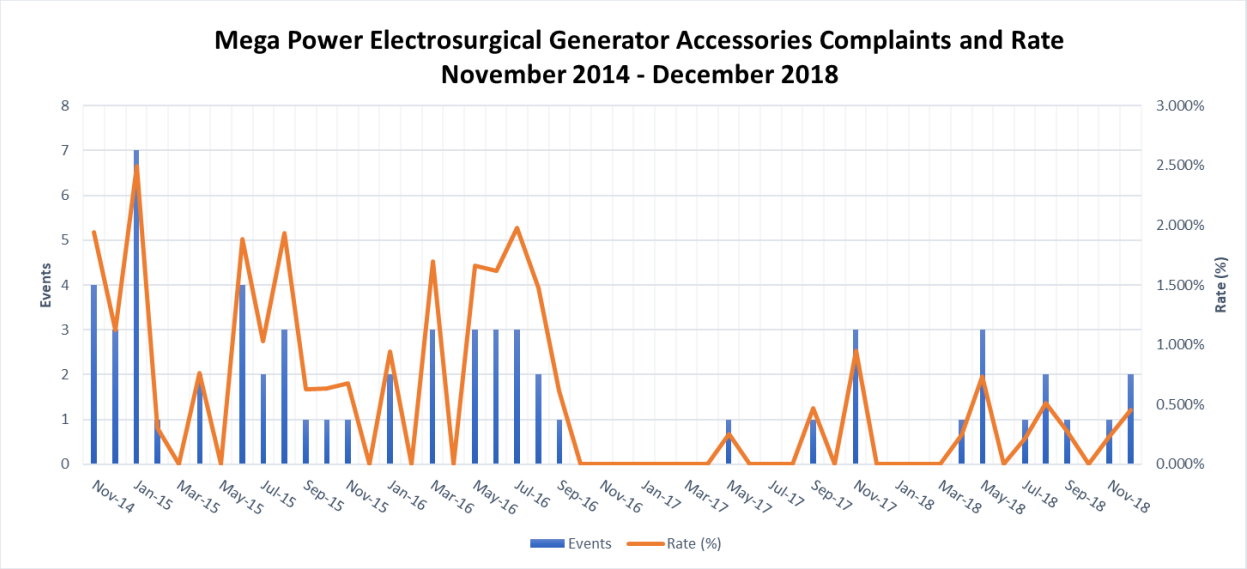


Table 7: Summary of Overall Mega Power Electrosurgical Generator Accessories Complaints

Complaint Summary	NOV 2014 – DEC 2015	JAN 2016 – DEC 2016	JAN 2017 – DEC 2017	JAN 2018 – DEC 2018	Total
Events (Total qtn involved)	29	17	5	10	61
Complaints (Unique Files)	29	17	5	10	61
WW Sales	3055	2238	3970	4786	14049
Complaint Rate (%)	0.9493%	0.7596%	0.1259%	0.2089%	0.4342%

6.6.2.1.2. MegaVac Smoke Evacuation Accessories

There were 113 complaint events received from November 2014-December 2018 reporting 113 issues with an overall complaint rate of 0.2309%. Figure 2 and Table 8 presents the total number of complaints, sales, and the complaint rate for the PMS Review period. The complaint counts captured in this graph reflect the total product quantity involved in the unique reported events.

Figure 2: MegaVac Smoke Evacuation Accessories Complaints and Rate

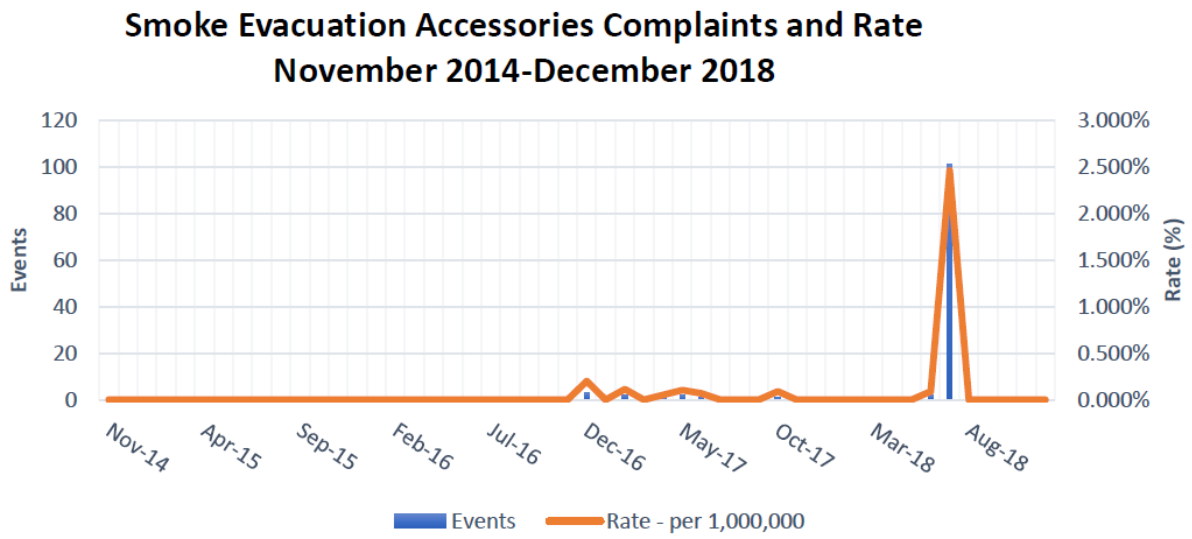


Table 8: Summary of Overall Smoke Evacuation Accessories Complaints

Complaint Summary	NOV 2014 – DEC 2015	JAN 2016 – DEC 2016	JAN 2017 – DEC 2017	JAN 2018 – DEC 2018	Total
Events (Total qtn involved)	0	3	7	103	113
Complaints (Unique Files)	0	3	7	4	14
WW Sales	0	1862	14438	32632	48932
Complaint Rate (%)	NA	0.0000%	0.0485%	0.3156%	0.2309%

6.6.2.1.1. MegaVac Smoke Evacuation Accessories

There were 608 complaint events received from November 2014-December 2018 reporting 608 issues with an overall complaint rate of 0.8157%. Figure 3 and Table 9 present the total number of complaints, sales, and the complaint rate for the PMS Review period. The complaint counts captured in this graph reflect the total product quantity involved in the unique reported events.

Figure 3: Megadyne Patient Return Electrode Accessories Complaints and Rate

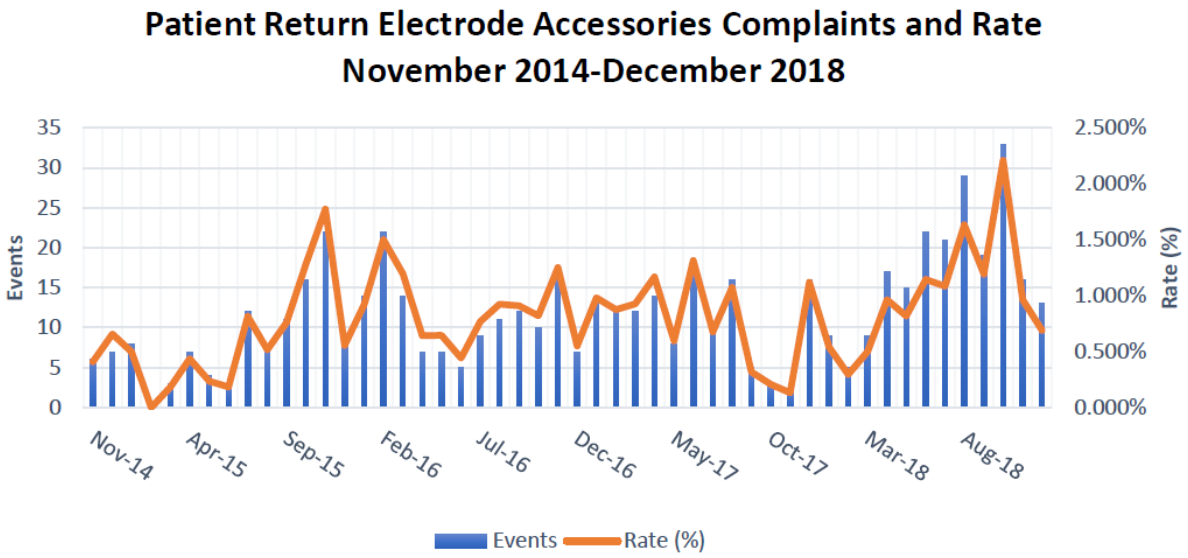


Table 9: Summary of Overall Patient Return Electrode Accessories Complaints

Complaint Summary	NOV 2014 – DEC 2015	JAN 2016 – DEC 2016	JAN 2017 – DEC 2017	JAN 2018 – DEC 2018	Total
Events (Total qtn involved)	118	137	132	221	608
Complaints (Unique Files)	114	134	130	209	587
WW Sales	21181	14686	17372	21301	75540
Complaint Rate (%)	0.5571%	0.9329%	0.7598%	1.0375%	0.8157%

6.6.2.2. Complaints Data by Category

6.6.2.2.1. Mega Power Generator Accessories

6.6.2.2.1.1 Product Experience Code

Table 10: Summary of Mega Power Electrosurgical Generator Accessories Complaints by provides a summary of the Product Experience Codes (PECs) that were reported during the PMS review period.

Table 10: Summary of Mega Power Electrosurgical Generator Accessories Complaints by Product Experience Code

Product Experience Code	Nov 2014-Dec 2015		Jan 2016-Dec 2016		Jan 2017-Dec 2017		Jan 2018-Dec 2018		Total	
	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)
Performance Failure Unknown	11	0.3601%	10	0.4468%	4	0.1008%	0	0.0000%	25	0.1779%
Intermittent	11	0.3601%	3	0.1340%	0	0.0000%	0	0.0000%	14	0.0997%
Damaged Product	5	0.1637%	3	0.1340%	1	0.0252%	2	0.0418%	11	0.0783%
Fit/Connection	2	0.0655%	1	0.0447%	0	0.0000%	0	0.0000%	3	0.0214%

Footswitch Does Not Activate System	0	0.0000%	0	0.0000%	0	0.0000%	0	0.0000%	2	0.0142%
Alarm Unspecified	0	0.0000%	0	0.0000%	0	0.0000%	0	0.0000%	2	0.0142%
Self-Activation	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0209%	1	0.0142%
Error Code Unspecified	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0209%	1	0.0142%
Bipolar Issue	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0209%	1	0.0142%
Generator Connection Issues	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0209%	1	0.0142%
Grand Total	**29**	**0.9493%**	**17**	**0.7596%**	**5**	**0.1259%**	**10**	**0.2089%**	**61**	**0.4342%**

6.6.2.2.1.2 Patient Code (Harm)

There were no Patient Codes (Harms) reported for Mega Power Electrosurgical Generator Accessories over the time period in this PMS Review. As a result, a PMS harms evaluation for the Mega Power Generator Accessories product family is not necessary at this time and was not performed.

6.6.2.2.1.3 Overall Complaint Analysis Conclusions

Overall complaints and rates were low. Over the review period there were 61 complaints for a rate of 0.4342%. Of those 61 complaints there were no Patient Codes reported. The product family review identified no new harms or hazards. The Performance Failure Unknown PEC was above the predicted rate.

6.6.2.2.2. MegaVac Smoke Evacuation Accessories

6.6.2.2.2.1 Product Experience Code

Table 11 provides a summary of the Product Experience Codes (PECs) for the MegaVac Smoke Evacuation Accessories that were reported during the PMS review period.

Table 11: Summary of Smoke Evacuation Accessories Complaints by Product Experience Code

Product Experience Code	Nov 2014-Dec 2015		Jan 2016-Dec 2016		Jan 2017-Dec 2017		Jan 2018-Dec 2018		Total	
	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)
Packaging Identification	0	N/A	0	0.0000%	0	0.0000%	101	0.3095%	**101**	**0.2064%**
Performance Failure Unknown	0	N/A	2	0.0000%	4	0.0277%	0	0.0000%	**6**	**0.0123%**
Aesthetic	0	N/A	1	0.0000%	1	0.0069%	0	0.0000%	**2**	**0.0041%**
Packaging Device Issue	0	N/A	0	0.0000%	0	0.0000%	1	0.0031%	**1**	**0.0020%**
Audio Issue	0	N/A	0	0.0000%	1	0.0069%	0	0.0000%	**1**	**0.0020%**
Customer Dissatisfaction	0	N/A	0	0.0000%	0	0.0000%	1	0.0031%	**1**	**0.0020%**
Damaged Product	0	N/A	0	0.0000%	1	0.0069%	0	0.0000%	**1**	**0.0020%**
Grand Total	**0**	N/A	**3**	**0.0000%**	**7**	**0.0485%**	**103**	**0.3156%**	**113**	**0.0020%**

6.6.2.2.2.2 Patient Code (Harm)

There were no Patient Codes (Harms) reported for MegaVac Smoke Evacuation Accessories over the time period in this PMS Review. As a result, a PMS harms evaluation for the MegaVac Smoke Evacuation Accessories product family is not necessary at this time and was not performed.

6.6.2.2.2.3 Overall Complaint Analysis Conclusions

Overall complaints and rates were low. Over the review period there were 113 complaints for a rate of 0.2309%. Of those 113 complaints there were no Patient Codes reported. The product family review identified no new harms or hazards. All reviewed rates were within the predicted rates.

6.6.2.2.3. Megadyne Patient Return Electrode Accessories

6.6.2.2.3.1 Product Experience Code

Table 12 provides a summary of the Product Experience Codes (PECs) for the Megadyne Patient Return Electrode Accessories that were reported during the PMS review period.

Table 12: Summary of Patient Return Electrode Accessories Complaints by Product Experience Code

Product Experience Code	Nov 2014-Dec 2015		Jan 2016-Dec 2016		Jan 2017-Dec 2017		Jan 2018-Dec 2018		Total	
	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)
Damaged Product	34	0.1605%	75	0.5107%	59	0.3396%	84	0.3943%	**252**	**0.3381%**
Performance Failure Unknown	43	0.2030%	28	0.1907%	20	0.1151%	6	0.0282%	**97**	**0.1301%**
Not Specified	0	0.0000%	0	0.0000%	0	0.0000%	66	0.3098%	**66**	**0.0885%**
Injury	17	0.0803%	13	0.0885%	18	0.1036%	5	0.0235%	**53**	**0.0711%**
Aesthetic	5	0.0236%	10	0.0681%	23	0.1324%	2	0.0094%	**40**	**0.0537%**
Cosmetic Nonconformance	0	0.0000%	0	0.0000%	0	0.0000%	14	0.0657%	**14**	**0.0188%**
Intermittent	5	0.0236%	5	0.0340%	2	0.0115%	0	0.0000%	**12**	**0.0161%**
Skin Lesion That Is Pressure Chemical or Thermal	4	0.0189%	3	0.0204%	2	0.0115%	0	0.0000%	**9**	**0.0121%**
Customer Dissatisfaction	0	0.0000%	0	0.0000%	0	0.0000%	9	0.0423%	**9**	**0.0121%**
Unintended Thermal Injury Less Than 2nd Degree	0	0.0000%	0	0.0000%	0	0.0000%	8	0.0376%	**8**	**0.0107%**
Alarming	1	0.0047%	3	0.0204%	2	0.0115%	0	0.0000%	**6**	**0.0080%**
Unintended Thermal Injury	0	0.0000%	0	0.0000%	0	0.0000%	5	0.0235%	**5**	**0.0067%**
Patient Related Issue	0	0.0000%	0	0.0000%	0	0.0000%	5	0.0235%	**5**	**0.0067%**
Misassembly	4	0.0189%	0	0.0000%	1	0.0058%	0	0.0000%	**5**	**0.0067%**
Red Lights Alarm	0	0.0000%	0	0.0000%	0	0.0000%	4	0.0188%	**4**	**0.0054%**
Electrical Shock	0	0.0000%	0	0.0000%	2	0.0115%	1	0.0047%	**3**	**0.0040%**
Diminished Power or Output	3	0.0142%	0	0.0000%	0	0.0000%	0	0.0000%	**3**	**0.0040%**
Packaging Device Issue	0	0.0000%	0	0.0000%	0	0.0000%	3	0.0141%	**3**	**0.0040%**
Flame Flash Fire	0	0.0000%	0	0.0000%	1	0.0058%	2	0.0094%	**3**	**0.0040%**
User Related Issue	0	0.0000%	0	0.0000%	0	0.0000%	2	0.0094%	**2**	**0.0027%**
Contamination	2	0.0094%	0	0.0000%	0	0.0000%	0	0.0000%	**2**	**0.0027%**
Assembly Disassembly Issue	0	0.0000%	0	0.0000%	0	0.0000%	2	0.0094%	**2**	**0.0027%**
Fit/Connection	0	0.0000%	0	0.0000%	1	0.0058%	1	0.0047%	**2**	**0.0027%**
Activation Issue	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0047%	**1**	**0.0013%**
Electromagnetic Interference	0	0.0000%	0	0.0000%	1	0.0058%	0	0.0000%	**1**	**0.0013%**
Packaging Identification	0	0.0000%	0	0.0000%	0	0.0000%	1	0.0047%	**1**	**0.0013%**
Grand Total	**118**	**0.5571%**	**137**	**0.9329%**	**132**	**0.7598%**	**221**	**1.0375%**	**608**	**0.8157%**

6.6.2.2.3.2 Patient Code (Harm)

Table 13 provides a summary of the Patient Codes (Harms) for the Megadyne Patient Return Electrode Accessories that were reported during the PMS review period.

Table 13: Summary of Patient Codes (Harms) for the Megadyne Patient Return Electrode Accessories

Patient Code (Harm)	Nov 2014-Dec 2015		Jan 2016-Dec 2016		Jan 2017-Dec 2017		Jan 2018-Dec 2018		Total	
	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)	N	Rate (%)
Injury	18	0.0850%	19	0.1294%	5	0.0288%	17	0.0798%	**59**	**0.0792%**
Potential Safety Hazard	0	0.0000%	12	0.0817%	0	0.0000%	0	0.0000%	**12**	**0.0161%**
Burn	0	0.0000%	0	0.0000%	2	0.0115%	0	0.0000%	**2**	**0.0027%**
Thermal Burn	0	0.0000%	0	0.0000%	1	0.0058%	0	0.0000%	**1**	**0.0013%**
Disfigurement	0	0.0000%	0	0.0000%	1	0.0058%	0	0.0000%	**1**	**0.0013%**
Burns Second Degree	0	0.0000%	0	0.0000%	1	0.0058%	0	0.0000%	**1**	**0.0013%**
Pain	0	0.0000%	0	0.0000%	1	0.0058%	0	0.0000%	**1**	**0.0013%**
Grand Total		**0.0850%**	**31**	**0.2111%**	**11**	**0.0633%**	**17**	**0.0798%**	**77**	**0.1033%**

Critical Analysis of Patient Return Electrode Accessories Patient Codes

"Injury" and "Potential Safety Hazard," were the highest reported Patient Codes (PCs) for the Patient Return Electrode Accessories included over the period in this PMS Review. These PC's are discussed in further detail below.

PC1. Injury: A total of 59 Injury events with a rate of 0.0792%were reported during the time periods included in this PMS report. These events were reviewed and evaluated. The reporting countries were USA (22) and no other event greater than 5. The reported PEC's for the Injury PC, were Injury (52), Damaged Product (5), Electrical Shock (1) and Flame Flash Fire (1). There was 4 MDR reportable event (Serious Injury) and no MDV reportable events. The patient code is addressed in the Risk Analysis ENG-RMF-021 Rev.009 under various "Injury" line items.

PC2. Potential Safety Hazard: A total of 12 Potential Safety Hazard events with a rate of 0.0161% were reported during the time periods included in this PMS report. These events were reviewed and evaluated. The reporting countries were Finland (5), USA (3) and no other event greater than 1. The reported PEC's for the Potential Safety Hazard PC, were Aesthetic (5), Performance Failure Unknown (2), Damaged Product (2), and no other PEC reported greater than 1. There was 1 MDR reportable event (Malfunction) and no MDV reportable events. The patient code is addressed in the Risk Analysis ENG-RMF-021 Rev.009 under various "Injury" line items.

Harm Evaluation Exercise

A total of 608 complaint events, with 77 identified Patient Codes, were reported on Patient Return Electrode Accessories from the November 2014 – December 2018 time period. These events were converted to event rate and compared against the respective predicated rate of occurrences as defined in the Risk Document (ENG-RMF-021 Rev 009) for Mega Soft family of Reusable Return Electrodes Analysis. As illustrated in the Harms Evaluation in Table 14, Appendix I, the rates of occurrence were at or below predicted. It should be noted that no new harms were identified within the Patient Return Electrode Accessories product family.

Table 14: PMS Harms Evaluation Worksheet for Megadyne Patient Return Electrode Accessories

Risk Document Number/Revision:		ENG-RMF-021 Rev. 009	
Data from Risk Document		Reported Harm Rate (from PMS Data)	Conclusion
Harms	Frequency of Occurrence		
Potential Safety Hazard (Injury/ Disfigurement)	Frequent (> 1% and < 10%)	(72 Rare) 0.0966%	Below Predicted
Thermal Burn/ 2nd Degree)	Frequent (> 1% and < 10%)	(4 Rare) 0.0054%	Below Predicted
Pain	≤ 0.1%	(1 Rare) 0.0013%	As Predicted

6.6.2.2.3.3 Overall Complaint Analysis Conclusions

Overall complaints and rates were low. Over the review period there were 608 complaints for a rate of 0.8157%. Of the 608 complaints there were 77 Patient Codes. The product family review identified no new harms or hazards. The product family is preforming as predicted.

6.6.2.3. FDA-MDR/MDV Data

6.6.2.3.1. Mega Power Generator Accessories

MDR Reportable Events

Of the 61 complaints for the Mega Power Generator Accessories, one complaint was MDR reportable for a malfunction during the December 2017 – November 2018 time period.

MDV Reportable Events

There were no reportable MDV's for Mega Power Generator Accessories during the PMS review period.

6.6.2.3.2. MegaVac Smoke Evacuation Accessories

MDR Reportable Events

Of the 113 complaints for the MegaVac Smoke Evacuation Accessories, 101 complaints were MDR reportable for a malfunction during the December 2017 – November 2018 time period.

MDV Reportable Events

There were no reportable MDV's for Mega Power Generator Accessories during the PMS review period.

6.6.2.3.3. Megadyne Patient Return Electrode Accessories

MDR Reportable Events

Of the 608 complaints for the Megadyne Patient Return Electrode Accessories, 13 complaints were MDR reportable with 9 Serious Injury and 4 Malfunctions.

MDV Reportable Events

Of the 608 complaints for the Megadyne Patient Return Electrode Accessories, 3 complaints were MDV reportable as "All Other Reportable Incidents.".

6.6.2.4. Death-Related Events

There were no deaths reported for any of the Megadyne Class I Accessory products during the PMS reporting period.

6.6.2.5. External Vigilance Data

External Vigilance is not applicable as technical documentation is available for the subject devices.

6.6.3. Actions/Alerts

6.6.3.1. Corrective and Preventive Actions (CAPAs)

The Corrective and Preventative Action process for the subject device is conducted under PR-0000385. In accordance with the procedure, a risk assessment is conducted to evaluate the significance of the risk of the issue and its associated impact. If the CAPA requires escalation, the appropriate management representatives are required to review and assess the escalation based on their scope of responsibility. For further details pertaining to the CAPAs, refer to applicable CAPA file in Table 15.

Table 15: Megadyne Class I Accessory Products CAPA Summary

CAPA Number	CAPA Title	CAPA Create Date	CAPA Closed Date	CAPA Status	CAPA Description	CAPA Root Cause(s)
CAPA-008537	2140J Connector Mislabeled	24 August 2018	N/A	Implementation	On July 3rd, 2018 a customer (Lynchburg General Hospital-Virginia) complained to Megadyne Complaint Analyst that a package labeled 2140J Lot # 183199 contained an incorrect part and supplied the picture of incorrect part. From the pictures, it was determined that the incorrect part was P/N 2145J.	Method / Process: Procedures not adequately defined: Procedural Gaps (Missing Steps) Man: Omission Errors

6.6.3.2. Escalations

There was 1 escalation (# 1266869) which resulted in CAPA-008537 summarized in Section 6.6.3.1.

6.6.3.3. Alerts

MHRA Review: A total of 2 alerts came back in the Medicines and Healthcare Products Regulatory Agency (MHRA) Database maintained by the Department of Health of the United Kingdom. The search was conducted on March 15, 2019 for “Megadyne,”. Nether of the 2 alerts were related to the Megadyne Class 1 Accessories for the period of November 2013 – December 2018.

6.6.3.4. Field Actions and Recalls

There were no Field Actions or Recalls for the Megadyne Class I Accessory product family during the PMS review period.

7. BENEFIT / RISK ANALYSIS

7.1. Clinical Benefits / Performance Analysis

Based on the nonclinical testing and the ongoing PMS data monitoring, the Megadyne Class I Accessory product family are safe and performing as intended as adjunctive accessory devices for other Class IIa and IIb devices described in Section 4.2 (which are not in scope of this CER). They have no diagnostic or therapeutic indications or contraindications independent of their intended adjunctive use. Therefore, no direct clinical benefits are anticipated other than allowing the Class IIa and IIb devices to function as intended which is a benefit to allow the index procedure to proceed. Per MDD Annex X, 1.1d of the European Council Directive 93/42/EEC (MDD), the body of evidence used to demonstrate conformity with the Essential Requirements and support the safety and performance of these Class I adjunctive accessory devices in accordance with their intended purpose includes non-clinical data (bench testing), in consort with risk management and PMS data which is continually monitored in the post-market phase. Clinical data is neither applicable, appropriate, nor required for demonstrating conformity with the EU Class I accessory devices in scope of this CER.

7.2. Clinical Risks / Safety Analysis

The CE marked Megadyne Class I Accessory Products are low risk devices that have been in clinical use for over 20 years. The accessory devices contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. They do not come in contact with the patient and do not contain any computer software.

Potential hazards and harms associated with Megadyne Class I Accessory Products in scope of this CER have been identified via the Megadyne, Inc. Risk Management Procedures. The output of the Risk Assessment procedure provides an objective Risk Assessment for these accessory devices in scope of this CER.

The identified risks with the use of the Class I accessory subject devices include patient harms from the parent device for which it is designed for use. These risks are identified in the Design Failure Mode and Effect Analysis (FMEA) and the Hazard Assessment for each of the product families. Megadyne, Inc. takes all necessary steps to ensure that risks are reduced as far as possible by applying the available State of the Art techniques in designing and manufacturing the target device to ensure safe usage. The applicable Risk Assessment documents are presented in Table 16.

Table 16: Risk Management Document(s)

Device	Risk Management Document Reference / Rev.
Reusable Patient Return Electrodes product codes: 0825, M2K01, M2K02, M2K03, M2K04, M2K05, M2K06, M2K07, M2K08, M2K09, PKIT001	FMEA/Failure Mode Effects Analysis: ENG-RMF-021 Rev 010 Hazard Assessment for the Mega 2000 and Mega Soft Family: ENG-RMF-022, Rev 003 Risk Management Report (RMR) for the Mega 2000 and Mega Soft Family: ENG-RMF-065 Rev 003
Mega Power product codes: 0075, 1300SJ, 1300U, 1400JJ, 1450J	Mega Power® Risk Management Plan: ENG-RMF-039 Risk Analysis for the Mega Power® Generator: ENG-RMF-018, Rev 009 Hazard Assessment for the Mega Power® Generator: ENG-RMF-019, Rev 001

Device	Risk Management Document Reference / Rev.
	Risk Management Report (RMR) for the Mega Power® Generator: ENG-RMF-042, Rev 002
Smoke Evacuator and Accessories product codes: 2140J, 2145J, 2150J, 2151J, 2211J, 2220J	Risk Management Plan - ZIP: ENG-RMF-043, Rev 006 Smoke Evacuation Electrosurgical Pencil and Accessories Hazards: ENG-RMF-044, Rev 002 Risk Management Report, Zip Pen and Accessories: ENG-RMF-036, Rev 004

7.3. Side-Effects Acceptability

The Megadyne Class I Accessory Products do not have direct contact with the patient. The PMS data for a 5-year period did not identify any new harms. Furthermore, a Harms Evaluation Exercise conducted as part of the PMS analysis found that the harms which were reported during the PMS review period occurred at rates equal to or less than anticipated rates found in the risk documentation. No patient safety related issues were identified as part of the PMS Harms Analysis.

7.4. Benefit-Risk Profile Acceptability

The data appraisal plan considers all data available (non-clinical test data and PMS data) for the subject devices and applicability of these data to the Essential Requirements. Nonclinical (benchtop), analytical, and PMS data are available to sufficiently demonstrate the safety and performance of the subject devices. As previously discussed, the Megadyne Class I Accessory Products have no direct diagnostic therapeutic indications or contraindications independent of their intended adjunctive use. Therefore, no direct clinical benefits are anticipated other than allowing the Class IIa and IIb devices, for which they are designed for use, to function as intended.

As demonstrated in the risk documentation and the PMS harms analysis in Section 6.6.2.2, the risks and potential harms associated with the subject devices are acceptable and the review of the data did not identify any new or previously unrecognized risks or harms. Furthermore, the risk and harms analysis has not resulted in the need to reconsider risk scores or required amendments to the product information, labeling, or warnings.

There were no deaths reported during the PMS review period. The post market surveillance data supports the rationale that the subject devices do not introduce any new risks.

Based on the results of the data analysis conducted in this CER, it is verified that the implemented risk control measures are sufficient and that no new or emerging risks have been identified that would render the Megadyne Class I Accessory Products as less than state-of-the-art for both safety and performance. State of the art was confirmed via passing pre-determined specifications and conformity with all applicable standards. Furthermore, it is verified that the risks have been reduced as far as possible over the lifetime of the device.

Based on the overall medical benefits (of allowing the devices for which they are designed for use to function as intended) and the possible harms identified from the reviewed data sources, it is determined that the benefits of the Megadyne Class I Accessory Products have been reduced as far as possible and the benefits of these very low risk devices outweigh the possible risks over the lifetime of the device.

8. CONCLUSION

Since the Megadyne Class I Accessory Products have been available in the EU for over 20 years, there is sufficient data available from nonclinical use as confirmed with continuous monitoring of data in the Post Market Phase (PMS) to demonstrate safety and performance. In accordance with Annex X, 1.1d of the European Council Directive 93/42/EEC (MDD), demonstration of conformity with Essential Requirements based on clinical data is not deemed appropriate for these low risk Class I accessory devices. The body of evidence used to demonstrate conformity with the Essential Requirements and support the safety and performance of these accessory devices utilized non-clinical data, risk management outputs, and PMS data. Clinical data is neither applicable nor required for these devices. These accessory devices contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. They do not come in contact with the patient and do not contain any computer software.

No new unanticipated, emerging, or unacceptable risks were identified from the PMS data or risk management assessment. These risks have been analyzed within the PMS report and assessed individually. All harms have been defined with their potential causes of failure and associated mitigation activities. Hazards that can lead to these Harms have been shown in the Risk Documentation to be mitigated to as far as possible after risk control measures have been implemented and verified.

In conclusion, it has been shown that there is sufficient objective evidence to establish the safety and performance of Megadyne Class I Accessory Products is maintained in the post market phase when used as intended. The data are adequate to assess the benefits and risks associated with the subject devices, concluding that the benefit-risk profile is acceptable. Megadyne, Inc. has undertaken all necessary steps to ensure that the residual risk factors associated with these accessory devices are mitigated by applying existing State-of-the Art techniques for the design, testing, and manufacturing of these medical devices to ensure safe usage and that the devices will perform as intended.

Therefore, based on Annex X, 1.1d of the European Council Directive 93/42/EEC (MDD), this clinical evaluation has established that the available non-clinical, PMS and risk management data are sufficient to establish conformity with all applicable Essential Requirements and confirm the safety and performance of the subject devices.

8.1. Rationale for no PMCF Studies for the Megadyne Class I Accessory Products

By definition, in accordance with MDD Annex X 1.1d, these devices do not need clinical data to confirm safety and performance. This CER is actively updated with data from post-market surveillance (PMS) in accordance with the Medical Device Directive MDD 2007/47/EC, MEDDEV 2.12/2 revision 2 and MEDDEV 2.7/1 revision 4. Megadyne, Inc. uses an established PMS system that monitors clinical safety and performance of the Megadyne Class I Accessory Products as part of its quality management system (QMS). Where applicable, any new clinically significant data detected from complaints, vigilance reports, safety reports (or any other source) are monitored and trended regularly. The data are critically and objectively analyzed with respect to the device's benefit-risk profile to confirm and maintain a high degree of protection of safety for the patient and user of these device accessories. These PMS data are incorporated into the CER regularly based on device classification and residual risk presented in the CER Frequency Update Matrix (Table 18).

Collectively, sufficient nonclinical data exist to support the safety and performance of the Megadyne Class I Accessory Products when used within their intended purpose and instructions. Therefore, no clinical data

or PMCF studies are required. The detailed justification for not conducting PMCF Studies for subject devices is presented in Table 17.

Table 17: Megadyne Class I Accessory Products Post Market Clinical Follow-up Studies Guide (per MEDDEV 2.12/2 Guidance)

Circumstances that may justify PMCF studies include, for example:	Yes/No
Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel	No
Significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed	No
High product related risk e.g. based on design, materials, components, invasiveness, clinical procedures	No
High risk anatomical locations	No
High risk target populations e.g. pediatrics, elderly	No
Severity of disease/treatment challenges	No
Questions of ability to generalize clinical investigation results	No
Unanswered questions of long-term safety and performance	No
Results from any previous clinical investigation, including adverse events or from post-market surveillance activities	No
Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g. hip implants in different ethnic populations	No
Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product	No
Risks identified from the literature or other data sources for similar marketed devices	No
Interaction with other medical products or treatments	No
Verification of safety and performance of device when exposed to a larger and more varied population of clinical users	No
Emergence of new information on safety or performance	No
Where CE marking was based on equivalence	No
PMCF Recommended (based on factors above indicating residual risk):	**No**

8.2. CER Frequency

The CER is an output of the clinical evaluation process, which is ongoing to ensure that safety and performance of medical devices are based on sufficient clinical evidence throughout the lifetime that the medical device is on the market (e.g. device lifecycle). For existing devices, the CER should be updated at planned intervals.

For the Megadyne Class I Accessory Products, the frequency of periodic updates was determined by completing the CER Frequency Matrix where the justification for the next periodic update is provided in Table 18. The justification was based on all subject devices in-scope for the clinical evaluation and considered the device risk category across all attributes (very low, low, medium, high as listed in the Matrix) considering worse-case scenarios in order to determine whether the device is well-established. The attribute of the “Highest Potential Risk to the Patient as a Result of Device Failure” defined the risk band (very low/low or medium/high).

In conclusion, the overall risk classification for these EU Class I accessory devices was deemed to be VERY LOW, where thus the planned periodic update for the CER will be every 5 years.

NOTE: CERs may require an off-cycle update in the event that new information is received with the potential to change the current evaluation.

Table 18. Megadyne Class I Accessory Products CER Frequency Matrix

CER Update Frequency - Risk Determination Matrix							
What attribute is addressing	**Attribute**	**Very Low**	**Low**	**Med**	**High**		
- characterizes patient health consequences associated with device failure	**Highest potential risk to patient as a result of device failure***	Limited (transient, minor impairment, or complaints) **OR** No adverse health consequences	Failure unlikely to cause or contribute to serious injury, or death under circumstances of normal use with results being temporary or reversible without medical intervention	Failure possibly could cause or contribute to serious injury, or death under circumstances of normal use that is likely reversible with medical / surgical intervention	Results in permanent impairment of body function or permanent damage to a body structure **OR** Life-threatening (death has or could occur) regardless of medical / surgical intervention	Device Risk Category	***High rating in any of these attribute categories mandates highest update frequency within risk band**
- characterizes # of complaint events per determined volume associated with device to provide evidence if device is not safe or is not performing	**Complaint Rate***	Negligible rate per time or volume	Low rate per time or volume	Medium rate per time or volume	High/Very High rate per time or volume		
- characterizes how long (theoretically, how often) subject device used for the intended use	**Subject Device Product Maturity**					Well-established Device Category	
- lower risk the longer the device is on market / more devices used	**# Units of worst case variant(s) sold / shipped since launch**	x > 10,000	1000 < x < 10,000	100 < x < 1000	x < 100		
- worst case = devices with highest potential risk to patient as a result of device failure	**Time on Market: Implantable Device:**	> 10 years	5 - 10 years	3 - 5 years	< 3 years		
	Time on Market: Non-Implantable Device:	> 5 years	3 - 5 years	1 -3 years	< 1 year		
- characterizes how long the equivalent device technology (design, mfg., materials) has been on the market	**Technological Maturity of Equivalent Device (if applicable)**						
	Time on Market: Implantable Device:	> 10 years	5 - 10 years	3 - 5 years	< 3 years		

- lower risk the longer the device is on market / more devices used	**Time on Market: Non-Implantable Device:**	> 5 years	3 - 5 years	1 -3 years	< 1 year	
- characterizes how well established the clinical science is (i.e. how long clinicians have been using similar devices for the intended use / technique)	**Maturity of Clinical Science**					
	Time of Clinical Use:	> 10 years	5 - 10 years	3 - 5 years	< 3 years	
- characterizes general risk of device	**MDR Device Classification**	I	IIa	IIb	III	Device Risk Category
- characterizes degree of device contact	**Degree and Duration of Device Invasiveness**	Non-Invasive Device No patient contact or exposure to device	Invasive Device (non-implantable, body orifice) Transient / Short-Term patient contact or exposure (seconds / minutes / Hours)	Surgically Invasive Device (non-implantable) Transient / Short-Term patient contact or exposure (seconds / minutes / Hours)	Surgical Implant Extended time frame of contact or exposure to the device (partially implantable devices that are implanted >30 days and/or fully implantable devices)	
- characterizes state of health (i.e. patient motivation/risk), not about the device	**Natural course and consequences of medical conditions if left untreated**	Limited (transient, minor impairment or pain) **OR** No adverse health consequences	Natural course unlikely to cause or contribute to serious injury, pain, or death	Natural course could possibly cause or contribute to serious injury, pain, or death	Natural course likely causes or contributes to serious injury, pain, or death	
- characterizes risk by anatomic area / physiological functions	**Anatomical location where device used**	No body contact	Body orifice, intact skin	All other anatomical locations	CNS, CCS	
- characterizes the Safety / Performance evidence for intended use / technique across lifetime - nominal (subject or equivalent) = low amount of data but sufficient to launch / update - ample (subject) = does not require equivalent device	**Clinical Data (quantity / quality)**	Clinical data was deemed not necessary (MDR Article 61 (section 10)	Nominal level I - III data on subject device and ample data on equivalent device across all indications / lifetime	No level I - III data on subject device and ample data on equivalent device across all indications / lifetime	No level I - III data on subject device and nominal data on equivalent device across all indications / lifetime	Well-established Device Category

CER Update Frequency - Risk Determination Matrix				
Attribute	**Very Low**	**Low**	**Med**	**High**

Highest potential risk to patient as a result of device failure*	Limited (transient, minor impairment, or complaints) **OR** No adverse health consequences	Failure unlikely to cause or contribute to serious injury, or death under circumstances of normal use with results being temporary or reversible without medical intervention	Failure possibly could cause or contribute to serious injury, or death under circumstances of normal use that is likely reversible with medical / surgical intervention	Results in permanent impairment of body function or permanent damage to a body structure **OR** Life-threatening (death has or could occur) regardless of medical / surgical intervention	*High rating mandates highest update frequency
CER Update Frequency Guide:	5 years	3 years	2 years	1 year	
Justification for selection: The CER Frequency for the Megadyne Class I Accessory Products CER is every 5 years. The Megadyne, Inc. accessory devices are low risk EU Class I devices. They contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. They do not come in contact with the patient.					
Background: The Megadyne Class I Accessory Products are well-established EU Class I legacy CE-Marked devices that have been shown to be safe and perform as intended. Based on the degree of technological/clinical maturity (over 20 years in EU) , there are no uncertainties or unanswered questions for the device and its intended use. Thus, the CER Frequency is designated as every 5 years.					

9. APPENDICES

9.1. Supporting References for Key Documents

Document Name	Document Number	Revision
Clinical Evaluation Report Procedure"	PR-0000277	Rev 18
Technical File: Patient Return Electrodes Reusable	RA-TECH-0003	Rev 001
Technical File: Mega Power	RA-TECH-0007	Rev 001
Technical File: Smoke Evacuation Pencil and Accessories	RA-TECH-0002	Rev 001
IFU: Reusable Foot Control Cable, 3 m (10 ft) - Product Code 0075	3000051-01	Rev 003
IFU: ULPA Filter with Fluid Trap - Product Code 2211J	3000190-01	Rev 003
IFU: Charcoal Filter (MEGA VAC™) – Product Code 2220J	3000191-01	Rev 002
IFU: Replacement Pigtail Cable - Product Code M2K07	3000124-01	REV 004
IFU: Mega 2000 (Product Code 0800)	3000046-03	Rev 003
IFU: Mega Soft, Mega Soft Dual (Product Codes 0830, 0835)	3000068-01	Rev 004
IFU: Mega Soft Pediatric (Product Code 0840)	3000141-01	Rev 003
Universal Plus Mega Soft CMR	MKT-CMR-034	Rev 001
Red Cable, Replaceable, Top Assembly – M2K-07	6020064-01	Rev 001
Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	IEC 60601-2-2	Rev 001
Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D 4169	Reb 002
CMR Mega Soft Universal Patient Return Electrode	CMR MKT-CMR-028	Rev 002
MEGA Soft Pad Corner Inner (pre-shot) Mold, TOYO ET-90VR2	ENG-PRT-027	Rev 001
Test Protocol, for IQ, OQ, & PQ for Mega Soft Pad Corner Outer Mold	ENG-PRT-314	Rev 001
CMR Mega Soft Universal Patient Return Electrode	CMR MKT-CMR-028	Rev 002
Compatible Cable, Top Assy 2.4m (8'-0)	6020161-01	Rev 001
Compatible Cable, Top Assy 4.4m (14'-4)	6020161-02	Rev 001

Document Name	Document Number	Revision
Megadyne Reusable Patient Return Electrode System	ENG-DMR-005	Rev 010
Universal PLUS Mega Soft	MKT-CMR-034	Rev 001
0075 Reusable Foot Control Cable new vendor Qualification	ENG-PRT-147	Rev 001
0075 Reusable Foot Control Cable new vendor Qualification	ENG-RPT-227	Rev 001
Dielectric Withstand of Medical Devices, Accessories and Cables	ENG-PRT-096	Rev 002
IEC 60601-2-2 5th Edition Leakage, HF and Mains Testing on 0075 Foot Controlled Cables	ENG-RPT-303	Rev 001
Mechanical Testing of Footswitch Cables	ENG-PRT-118	Rev 001
Test Report, Mechanical Testing of Footswitch Cables.	ENG-RPT-193	Rev 001
Mechanical Testing of 1450 Footswitch Cable	ENG-PRT-158	Rev 001
Test Report, Mechanical Testing of 1450 Footswitch Cable	ENG-RPT-240	Rev 001
REPORT, FILTER FIT COMPATIBILITY TEST	ENG-RPT-556	Rev 001
Product Specification Verification Test Report II, Zip Pen	ENG-RPT-558	Rev 001
POST MARKET SURVEILLANCE REPORT (PMSR) FOR MEGA POWER ELECTROSURGICAL GENERATOR ACCESSORIES, SMOKE EVACUATION ACCESSORIES, AND REUSABLE ELECTRODE ACCESSORIES REPORT	RA-REC-019	Rev 001
POST MARKET SURVEILLANCE PLAN (PMSP) FOR MEGA POWER ELECTROSURGICAL GENERATOR ACCESSORIES, SMOKE EVACUATION ACCESSORIES, AND REUSABLE ELECTRODE ACCESSORIES PLAN	RA-REC-018	Rev 001
2140J Connector Mislabeled	CAPA-008537	--
Megapower Risk Analysis	ENG-RMF-018	Rev 012
Megapower Risk Management Plan	ENG-RMF-039	Rev 004
Megapower Risk Management Report	ENG-RMF-042	Rev 002
Mega Soft Pad Family Hazard Assessment Summary	ENG-RMF-022	Rev 003
Mega Soft Pad Family Risk Analysis	ENG-RMF-021	Rev 010
Risk Management Report for Mega Soft Family	ENG-RMF-065	Rev 003
Smoke Evacuation Electrosurgical Pencil and Accessories Hazard	ENG-RMF-044	Rev 002

Document Name	Document Number	Revision
Risk Management Plan - ZIP	ENG-RMF-043	Rev 006
Risk Management Report, Zip Pen and Accessories	ENG-RMF-036	Rev 004
Device Master Record: Megadyne Reusable Patient Return Electrode System	ENG-DMR-005	Rev 010
Device Master Record: Electrosurgical Generator, Mega Power	ENG-DMR-008	Rev 009
Device Master Record: SMOKE EVACUATION PENCIL AND ACCESSORIES	ENG-DMR-012	Rev 008

9.2. Product Codes

Product Code	Description	MDD Device Class	MDD Rule #	Sterility	CE Mark Date	Technical Document Number
0825	MEGA 2000™ Sheath	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K01	Mega Soft Reusable DetachaCable™ Cord, Standard Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K02	Mega Soft Reusable DetachaCable™ Cord, Standard Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K03	Mega Soft Reusable DetachaCable™ Cord, Phone Plug Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K04	Mega Soft Reusable DetachaCable™ Cord, Phone Plug Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K05	Mega Soft Reusable DetachaCable™ Cord, Extended Phone Plug Connector, 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K06	Mega Soft Reusable DetachaCable™ Cord, Argon Beam Connector, 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K07	Replacement Pigtail Cable	I	Rule 1	Non-Sterile	10 April 2013	RA-TECH-0003
M2K08	DetachaCable™ Cord, Compatibility, Mega Soft 2.4m (8.0 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
M2K09	DetachaCable™ Cord, Compatibility, Mega Soft 4.4m (14.4 ft.)	I	Rule 1	Non-Sterile	13 January 1999	RA-TECH-0003
PKIT001	MEGA SOFT™ Patch Kit	I	Rule 1	Non-Sterile	23 October 2002	RA-TECH-0003
0075	Reusable Foot Control Cable, 3 m (10 ft)	I	Rule 1	Non-Sterile	12 May 2005 [A]	RA-TECH-0007
1300SJ	Mega Cart with Top Shelf	I	Rule 1	Non-Sterile	12 May 2005 [A]	RA-TECH-0007
1300U	Mega Cart	I	Rule 1	Non-Sterile	12 May 2005 [A]	RA-TECH-0007
1400JJ	Monopolar Footswitch (3 m cable)	I	Rule 1	Non-Sterile	12 May 2005 [A]	RA-TECH-0007
1450J	Bipolar Footswitch (3 m cable)	I	Rule 1	Non-Sterile	12 May 2005 [A]	RA-TECH-0007
2140J	MegaVac Connector	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002
2145J	22mm Male to 10mm Male Connector	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002
2150J	Universal Connector	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002
2151J	22mm ID Tube Connector	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002
2211J	Ulpa Filter	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002
2220J	Charcoal Filter (MEGA VAC™)	I	Rule 1	Non-Sterile	November 2003 [B]	RA-TECH-0002

A Date of Mega Power regulatory clearance.

B Date of MegaVac regulatory clearance

9.3. Literature Search Results

9.3.1. Systematic SOA Search

Energy Devices
Library State-of-the-Art Literature Search Results
November 2017

Condition/Surgical Job: Energy Devices for cutting, dissecting and coagulating tissue

Target Therapy: Electrosurgical, bipolar, monopolar, advanced bipolar, ultrasonic devices

Ref: SOA Outline November 2017

Date Search run: November 27, 2017

Contains:

Total results: 538 items

- 527 Articles from Ovid; QUOSA VL Link
- 7 Books/Chapters from Springer Books (Table and links below with full-text in VL)
- 4 Guidelines (Table and links below – non-Ovid)

Databases: Embase/Medline in OVID

Search Date Limitation: 2006 to present (November 2017)

Search Strategy:

EMBASE/MEDLINE in OVID

Embase 1996 to 2017 Week 47

Ovid MEDLINE(R) 1946 to November Week 3 2017

Ovid MEDLINE(R) Epub Ahead of Print November 22, 2017

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations November 22, 2017

Ovid MEDLINE(R) Daily Update November 22, 2017

#	Search Statement	Results
1	((energy or energetic or hemostatic or haemostatic) adj3 (device* or instrument* or source* or modalities or modality or treatment*)).ti,ab.	42233
2	(surgery or surgical or laparoscop*).ti,ab.	3316576
3	1 and 2	3337

4	(bipolar or ultrasonic* or ultrasound or harmonic* or electrosurg* or rf or radiofrequency or monopolar or laser or "argon beam").ti,ab.	1247325
5	((energy or vessel or tissue) adj3 (sealing or cut or cutting or dissect* or coagulat*)).ti,ab.	15435
6	4 and 5	3925
7	3 or 6	7036
8	7 not ablation.ti,ab.	5889
9	(guideline or practice guideline).pt. use ppez	32317
10	(guideline* or consensus or "position paper" or "position statement").ti.	188240
11	9 or 10	204611
12	8 and 11	19
13	(meta-analysis or "meta analysis" or metaanalysis or "systematic review").ti.	280255
14	"meta analysis (topic)"/ or "systematic review (topic)"/	51663
15	cochrane*.jn.	28115
16	cochrane.so.	16778
17	13 or 14 or 15 or 16	352520
18	8 and 17	106
19	(comparative or comparison or versus or vs or comparing).ti.	1298530
20	comparative study/	2470482
21	19 or 20	3213459
22	8 and 21	924
23	review.pt.	4364733
24	8 and 23	623
25	12 or 18 or 22 or 24	1533
26	limit 25 to yr="2006 -Current"	1111
27	remove duplicates from 26	692
28	limit 27 to english language	640
29	conference abstract.pt.	2773711
30	conference review.pt.	8402
31	28 not (29 or 30)	537

Within the above search strings, results from set 31 were exported to Quosa.

Notes on Ovid commands and operators:

/	indicates a subject heading
/su	a subject heading further focused by a subheading, su = surgery
*	truncation symbol (any number of characters)
adj	requires adjacency in the stated direction only
adjN	requires that terms be within N words of each other (in either direction)
exp	includes all terms in the hierarchy below the named subject heading
.mp.	searches the following fields for the term: title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name
.ti.	term must appear in the article title
.ab.	term must appear in the abstract of the article
.pt.	publication type
emef	abbreviation for Embase database; "use emef" isolates results to that database
ppez	abbreviation for MEDLINE database; "use ppez" isolates results to that database

After de-duplication, 532 articles remain for review.

All article citations with full-text links from Ovid are listed at the end of this document, following the Book and Guideline tables.

Book Search

Date Search Run: November 27, 2017

Source	Search Terms	Results
Springer Books	(Content Type=book chapters) Discipline=Medicine & Public Health) "energy AND (surgical OR surgery)" "ultrasonic devices" "(ultrasound or ultrasonic) AND bipolar"	Book: Feldman L., Fuchshuber P., Jones D. (Kavanagh et al.) The SAGES Manual on the Fundamental Use of Surgical Energy (FUSE). Springer, New York, NY (2012) Table-of-contents Chapter: Grochola L.F., Vonlanthen R. (2016) Surgical Energy Devices or Devices for Hemostasis. In: CLAVIEN PA., Sarr M., Fong Y., Miyazaki M. (Kavanagh et al.) Atlas of Upper Gastrointestinal and Hepato-Pancreato-Biliary Surgery. Springer, Berlin, Heidelberg (pp 37-44) Chapter: Wall J., Gertner M.E. (2008) Energy Transfer in the Practice of Surgery. In: Norton J.A. et al. (Kavanagh et al.) Surgery. Springer, New York, NY (pp 2345-2354)

		Chapter: Youn YK., Lee K.E., Choi J.Y. (2014) New Energy Sources in Surgery. In: Color Atlas of Thyroid Surgery. Springer, Berlin, Heidelberg (pp 137-145) Chapter: Zuker N.B., Gayet B. (2012) Laparoscopic Hepatic Transection Using Ultrasonic Scalpel and Bipolar Forceps. In: Di Carlo I. (Kavanagh et al.) Open, Laparoscopic and Robotic Hepatic Transection. Springer, Milano (pp 129-133) Chapter: Tanos V., Neofytou M., Pattichis C. (2016) Haemostasis in Minimal Invasive Gynaecological Surgery Energies: Technical Aspects, Safety and Efficacy. In: Kyriacou E., Christofides S., Pattichis C. (Kavanagh et al.) XIV Mediterranean Conference on Medical and Biological Engineering and Computing 2016. IFMBE Proceedings, vol 57. Springer, Cham (pp 1054-1057) Chapter: Böhm B., Milsom J.W., Nakajima K. (2006) Surgical Energy Sources. In: Milsom J.W., Böhm B., Nakajima K. (Kavanagh et al.) Laparoscopic Colorectal Surgery. Springer, New York, NY (pp 20-47)

Guidelines (additional guidelines not found in Ovid)

Date Search Run November 27, 2017

Source	Search Terms	Results
NICE Guidelines	Surgical energy Ultrasonic bipolar	Tonsillectomy using ultrasonic scalpel (2006)
National Guideline Clearinghouse	Energy devices	Guideline for safe use of energy-generating devices (2016) [summary]
Association of Surgical Technologists (AST)	Electrosurgical units	AST Standards of Practice for Use of Electrosurgery (2012)
European Society of Gastrointestinal Endoscopy (ESGE)	Electrosurgical units	European Society of Gastrointestinal Endoscopy (ESGE) guideline: the use of electrosurgical units (2010)

Form (Non-PPE) 100503977 Rev 5
Quality System CO: 100740462
Franchise Clinical Evaluation Report Template (Shared)

Contains: 527 Documents
Date: November 28, 2017
Sort: Author (Ascending)

9.3.2. Systematic Literature Review Search

Not applicable.

Per MDD Annex X (sec. 1.1d), the body of evidence used to demonstrate conformity with the Essential Requirements and support the safety and performance of the Megadyne Class I Accessory Products in accordance with their intended purpose includes non-clinical bench testing data, 5-year PMS data, and risk management data. A systematic literature review was not conducted as clinical data is neither applicable nor required for the Megadyne Class I Accessory Products in scope of this CER.

9.4. Bibliography

9.4.1. SOA Included Articles & General Articles

Alkatout, I., Schollmeyer, T., Hawaldar, N.A., Sharma, N., and Mettler, L. (2012). Principles and safety measures of electrosurgery in laparoscopy. JSLS : Journal of the Society of Laparoendoscopic Surgeons *16*, 130-139.

AORN (2012). Recommended Practices for Electrosurgery 99-118. In Perioperative Standards and Recommended Practices: Equipment and Product Safety.

AST (2012). AST Standards of Practice for Use of Electrosurgery (Association of Surgical Technologists Education and Professional Standards Committee.).

Baggish, M. (2012). Major laparoscopic complications: A review in two parts. Journal of Gynecologic Surgery *28 (5)*, 315-332.

Binsaleh, S. (2011). Evaluation of hemostatic AIDS in laparoscopic nephron-sparing surgery. Thescientificworldjournal *11*, 133-141.

Broughton, D., Welling, A.L., Monroe, E.H., Pirozzi, K., Schulte, J.B., and Clymer, J.W. (2013). Tissue effects in vessel sealing and transection from an ultrasonic device with more intelligent control of energy delivery. Medical devices *6*, 151-154.

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Schwaitzberg, S.D. (2012). Evolutions and Revolutions in Surgical Energy. In The SAGES Manual on the Fundamental Use of Surgical Energy (FUSE), L. Feldman, P. Fuchshuber, and D.B. Jones, eds. (New York, NY: Springer New York), pp. 3-13.

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9.4.2. Literature Included Articles (Subject Devices)

Not applicable/Not conducted. See Section 9.3.2 for rationale.

9.4.3. Literature Excluded Articles (Subject Devices)

Not applicable/Not conducted. See Section 9.3.2 for rationale.

9.5. Abbreviations

Abbreviation	Definition
AORN	Association of peri Operative Registered Nurses
CAPA	Corrective and Preventative Action
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
CV	Curriculum Vitae
DOI	Declaration of Interest
EEC	European Economic Community
ER	Essential Requirements
ESU	electrosurgical unit
EU	European Union
FMEA	Failure Modes and Effects Analysis
IFU	Information for user
MAUDE	Manufacturer and User Facility Device Experience
MDD	Medical Device Directive
MDR	Medical Device Reporting
MDV	Medical device vigilance
MHRA	Medicines and Healthcare Products Regulatory Agency
MIS	Minimally invasive surgery
OR	Operating Room
PC	Patient Code
PEC	Product Experience Code
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Experience and Surveillance
RBA	Risk Benefit Analysis
RF	Radiofrequency
RMR	Risk Management Report
RN	Registered Nurse
ROC	Route of conformity
SOA	State of the art
WW	Worldwide

9.6. CER Team

Role	Name
Medical Affairs Evaluator	Dr. Raymond Fryrear
Regulatory Affairs Evaluator	Kim Shoemaker
Medical Operations Evaluator / CER Author	Orlando Padilla
Post Market Surveillance	Katharine Seppa
Clinical Research	N/A
Risk Management / Quality	Scot Harris
R&D / Product Development	N/A – Legacy Devices
Other:	N/A

9.7. CV Of Medical Affairs (MA) Evaluator

NAME: Raymond S Fryrear II, M.D.

ADDRESS: Ethicon – 4545 Creek Road, Cincinnati, Ohio 45242

CONTACT: Cell (803) 391-6702

EMAIL: **rfryrear@its.jnj.com**

EDUCATION:

B.S.	1997	University of Memphis, Memphis, TN Major: Dual Biology/Chemistry
B.A.	2003	Trinity College, Dublin Ireland Major: Life Sciences
M.D.	2003	Trinity College of Medicine, Dublin Ireland Major: Medicine/Surgery

CERTIFICATION:

2005-Present
- Ohio Medical Licensure - pending
- South Carolina Medical Licensure
- American Board of Surgery BE
- Minnesota Medical Licensure
- BLS/ACLS
- ATLS
- ECFMG Certification

2016 Robotic Thoracic Surgery Certification

2015 Robotic Colon-Rectal Surgery Certification

2014 Robotic Surgery Certification

2012. Laparoscopic Hepatopancreaticobiliary Surgery

2011. Advanced Laparoscopic General Surgery

2009. Fundamentals of Laparoscopic Surgery

1997. Investment Banking Licensure – Series 7 & 63

1996. Polysomnography Registry Eligible

Electroencephalography Registry Eligible

INDUSTRY:

2019-Present Vice President and Integrated Platform Lead – Medical, Clinical, and Pre-Clinical Affairs, Ethicon-EndoSurgery - Cincinnatti OH

- Leads and inspires an organization of approximately 15-20 Medical, Clinical, Pre-clinical Affairs professionals. Accountable for ensuring that the Medical, Clinical and Pre-Clinical organization works in a harmonized, efficient way to drive customer satisfaction and partnership with cross-functional teams and the regional Regulatory, Medical and Clinical groups.
- Drives global innovation agenda (i.e. the short and long term strategic directions) across Ethicon's EndoMechanical, Energy and Torax Platforms through strategic accountability, alignment, and leadership with the following innovation leaders and business partners: Global Strategic Marketing, New Business Development, R&D, Regulatory, HEMA, Quality and Supply Chain, leveraging deep medical and (pre-)clinical expertise.
- Ensures team is successful in establishing long-term product opportunities, as well as unmet medical needs, designing inputs and evidence needs for development programs and post market products.
- Delivers on the portfolio's evidence strategies: Able to conduct gap analysis and data generation strategies to support the brand from a commercial, medical and market access perspective.
- Conceive and deliver clinical and pre-clinical studies of the highest scientific quality, within timelines and budgets. Align strategy, budget and resource allocation in close partnership with the cross-functional and regional partners in Regulatory and Medical and (Pre-) Clinical Affairs Operational Groups, as well as integrate the health economic and market access aspects, to allow market leadership while insuring patient safety.
- Develop and implement evidence generation strategies (Pre-and Post-Market approval- studies, Investigator Initiated, Real World Evidence) aligned to the needs of the R&D, Regulatory and Commercial organization.
- Plan and bring timely resources on board (internal and external).
- Explore new trends in data-collection (Real World Data, Predictive Analytics…)
- Lead clinical scientific discussions with regulatory agencies / notified bodies to drive support of the clinical and regulatory strategy, including proposed clinical investigations; review process of clinical evidence generated for marketing authorization, line extensions, etc, including during sponsor regulatory inspections.
- Oversee Life Cycle Medical and Clinical affairs (e.g. copy review, medical information requests, medical/clinical input CERs, etc.)
- Responsible for talent attraction development engagement and management.

HOSPITAL APPOINTMETNTS:

2017-2019 General Surgery, Chief of Surgery, Lexington Medical Center - Columbia, SC

2015-2019 General Surgery, Chief of Robotic Surgery, Lexington Medical Center - Columbia, SC

2011-2019 General Surgery Staff, Lexington Medical Center - Columbia, SC

2006-2011 General Surgery Residency, Mayo Clinic - Rochester MN

2005-2006 Internal Medicine Internship, Mayo Clinic - Rochester MN

2004-2005 General Surgery Sub-Internship: Exempla St Joseph Hospital - Denver CO.

2003-2004	Pathology Research Fellowship: Wake Forest University Baptist Hospital - Winston-Salem, NC
2002	Interventional Radiology Subinternship: Johns Hopkins Medical Institute - Baltimore MD
2001	Neurosurgery Subinternship: Cleveland Clinic Foundation - Cleveland OH
2001	Neurosurgery Research Fellowship: Cleveland Clinic Foundation - Cleveland OH
2001	Hematology/Oncology Research Elective: St Jude Children's Research Hospital - Memphis TN
2000	Neurosurgery Elective: St Jude Children's Research Hospital and Semmes Murphy Neurosurgical Clinic - Memphis TN
1997-1998	Investment Banker, Vining Sparks Investment Banking Group - Memphis, TN
1993-1997	Neuroscience Center Developer and Neuroscience Specialist, LeBonheur Children's Hospital - Memphis, TN
1989-1993	Talent Acquisition Leader, Federal Express Corporation - Memphis, TN
1986-1989	Chief Operating Officer, Crystal Industries/Peck Daniels Corporation - Memphis, TN

SOCIETY MEMBERSHIPS:

2014-Present	International Hernia Collaboration The Americas Hernia Society Quality Collaborative Robotic Surgery Collaboration SAGES Robotic Surgery Masters Program Collaboration SAGES Colorectal Surgery Masters Program Collaboration Robotic Colorectal Surgery Group Society of Robotic Surgery
2011-Present	South Carolina Medical Society
2007-Present	Society of Vascular Surgery
2006-Present	American College of Surgeons
2005-Present	American College of Physicians
2005-Present	Minnesota Medical Association
2003-Present	The International Society of Dermatopathology
2001-2003	Trinity College Student Medical Journal, Editor
1998-2003	International Medical Student Association
1998-2003	Medical Defense Union
1998-2003	Trinity College Medical Association
1998-Present	American Medical Association
1995-1997	Alpha Epsilon Delta Pre-Medical Honor Society, President
1995-2000	Golden Key National Honor Society, Vice President

PUBLICATIONS/PRESENTATIONS/POSTER SESSIONS:

1. Perspectives in Vascular Surgery, Case Report: Endograft Collapse, Andrew Knott M.D., Manju Kalra M.D., Raymond S. Fryrear II M.D., Submitted 2008.
2. Annals of Plastic Surgery, Clinical Experience with the Anconeus Muscle Flap: Advantages for Coverage of Defects about the Elbow, Raymond S. Fryrear II M.D., Steven L Moran M.D., In-Press 2008.

3. ASSH Pocket Manual, Avascular necrosis in the carpus and phalanges, Steven L. Moran M.D., Raymond S. Fryrear II M.D., **Book Chapter**: In-Press 2008.
4. World Journal of Surgery, Surgery for Cushing's Syndrome: An Historical Review and Recent Ten-year Experience, Porterfield JR, Thompson GB, Young WF, Chow JT, Fryrear RS, van Heerden JA, Farley DR, Atkinson JR, Meyer FB, Abboud CF, Nippoldt TB, Natt N, Erickson D, Vella A, Carpenter PC, Richards ML, Carney JA, Larson D, Schleck C, Churchward M, Grant CS In Press 2008.
5. AM J Dermatopathology, Early Juvenile Xanthogranuloma Clinically Mimicking Infantile Fibrosarcoma, Raymond S Fryrear, M.D., Omar Sangueza, M.D., 26(2):138, April 2004.
6. J AM Acad Dematology, Rapid onset of cutaneous squamous cell carcinoma of the penis in a patient with psoriasis on Etanercept, Raymond S Fryrear II, M.D., Anna Kay Wiggins, M.D., Gil Yosipovitch, M.D., Omar Sangueza, M.D., 2005 Aug;53(2):354-5.
7. JVIR, Endovascular treatment of ruptured aneurysms, Kieran J Murphy, M.D., Raymond Fryrear, B.S., Phillipe Gailoud, M.D., March 2005.
8. JVIR, The double density technique of increased visualization of cement during vertebroplasty, Kieran J Murphy, Amit D Malhotra, Raymond S Fryrear II, Philippe Gailloud, J Vasc Interv Radiol 2005 16: 425-426.
9. JVIR, Percutaneous vertebroplasty for compression fracture in an HIV-infected patient. Murphy KJ, Malhotra AD, Parker MW, Fryrear RS, Khandelwal N, Gailloud P, Morgan RH, 2004 Dec;15(12):1487.
10. JVIR, Spontaneous vertebral arterial venous fistula at the V4 segment treated by a combination of endovascular coiling and stenting, Murphy KJ, Fryrear RS, Gailloud P, March 2005.
11. CNS Philadelphia, Pennsylvania, A standardized biomechanical comparison of interbody fusion cages, Ferrara LA, Secor JL, Fryrear R, September 2002.
12. SRS Seattle Washington, A standardized biomechanical comparison of interbody fusion cages, Ferrara LA, Secor JL, Fryrear R, September 2002.
13. Textbook of Neurological Surgery: Principals and Practices. Invasive Epilepsy Monitoring in Pediatric Patients, Boop F, Fryrear R, **Book Chapter**: Lippincott Williams & Wilkins Published September 2002.
14. Annual Pediatric Medical Student Research Meeting, The prevalence of childhood obesity in Ireland, Fryrear RS, McKenna F, Bell L, Chong V, Mak G, Peirce J, July 2002.
15. IMAST, Montreus Switzerland. A standardized biomechanical comparison of interbody fusion cages, Ferrar LA, Secor JL, Fryrear R, May 2002.
16. ISSLS, Cleveland Ohio. Subsidence and push-out resistance of interbody fusion cages. Ferrara LA, Secor JL, Fryrear RS, Whitefield M, July 2002.
17. Joint Section. Orlando, Florida, A standardized biomechanical assessment of the push-out strength of threaded interbody fusion cages. Ferrara LA, Secor JL, Fryrear RS, Whitfield M, February 2002.
18. Global Spine: Surgical Principals and the Latest Techniques. Percutaneous pedicle screws; techniques and results, Foley KT, Fryrear RS. Maui, Hawaii July 2002.

19. Sixth Annual Detroit Neurosurgery Symposium. Percutaneous pedicle screw replacement. Detroit, Michigan, Foley KT, Fryrear RS. September 2002.
20. American Association of Neurological Surgery. Atlanta, Georgia. Slit Ventricle Syndrome in children. Sanford RA, Muhlbauer MS, Igarashi M, Thomas E, Fryrear RS. 2001
21. American Association of Neurological Surgery: San Francisco, CA. Division of the transverse sinus and tentorium cerebelli to allow vault expansion and posterior fossa decompression in the treatment of Arnold Chiari Malformation. Burson T, Muhlbauer MS, Sanford RA, Fryrear RS. February 2000.
22. Pharmacology Medical Student Research Meeting. Dublin, Ireland. The role of endothelin in arteriosclerosis. 2000.
23. Annual Physiology Medical Student Research Meeting. Dublin, Ireland. The role of adjuvant haemostatic support with Protein-C replacement therapy in Pupura Fulminans associated Meningococcemia. Fryrear RS, Gallagher J, Wolfe E, Kong B, Jain A, Smith O. 1999.
24. CANCER. Peritoneal metastases in children with cancer. Kaste SC, Mariana N, Fryrear R, Jedlund GL, Jones L, Poe D, Jenkins JJ III, 1998 Jul 15;83(2):385-90.
25. CANCER, Breast masses in women treated for childhood cancer, Kaste SC, Hudson MM, Jones DJ, Fryrear RS, Greenwald CA, Fleming ID, Pratt CB, 1998 Feb 15;82(4):784-92.
26. American Association of Neurological Surgery. San Diego, CA, Placement of On/Off Switches in Post-Tumoral Hydrocephalus, Donahue D, Fryrear RS, Sanford RA, Muhlbauer MS. April 1994.

RESEARCH IN PROGRESS: AVAILABLE UPON REQUEST.

HOBBIES & INTERESTS:

Triathlons, Martial Arts (Aikido), Competition Field Trials, Snow skiing, Hiking, Golf, Tennis, Music and Theater.

LANGUAGE:

Spanish – currently limited due to lack of usage, but previously fluent.
French – same as above.

OTHER AWARDS/ACCOMPLISHMENTS:

Residency:

Society for Vascular Surgery Scholarship, 2007
Silver Retractor Award, 2007

Medical School:

Cofounder of the Trinity Medical Student Journal
Editor of the Trinity Medical Student Journal
Distinction in Neuroanatomy, Physiology, and Pharmacology
Trinity Book Prize for overall honors 3rd Year

Undergraduate:

President of AED Premedical Honor Society
Vice President of Golden Key National Honor Society
Pre-Medical Student of the Year, 1996
Dean's List each semester

9.8. CV Of Regulatory Affairs (RA) Evaluator

Kimberly Shoemaker, RAC

Profile

- 25+ years experience in the health care industry, including In Vitro Diagnostics and Medical Devices serving in diversified roles in Research and Development, Quality and Regulatory Affairs.
- Business Leader with expertise in Regulatory Affairs demonstrating a solid track record
- Highly driven to achieve and exceed results and drive growth in developed and emerging markets
- Strong interpersonal skills with the ability to collaborate with global business partners to align priorities and mitigate risk and business continuity in a dynamic regulatory environment
- Excellent verbal and written communication skills, resulting in successful interfacing with regulatory authorities
- Demonstrate expertise and strong people development skills, with the ability to maintain a highly engaged team and high retention rate

Leadership Skills Summary

- Results and Performance Driven
- Strategic and Influencing
- Organization and Talent Development
- Collaboration and Teaming
- Integrity and Credo Based Actions
- Sense of Urgency

Professional Experience

Ethicon Endo-Surgery, InC / ETHICON, LLC (Cincinnati, OH) 2001-Present

WW Senior Director, Regulatory Affairs – Platform Lead

(2014-Present)

- Member of the Platform Leadership Teams and Project Sponsor (New Product Development) for Ethicon platforms (currently Endomechanical and Energy; prior responsibility included Robotics); provide advice, guidance and analysis of critical projects and the global regulatory environment;
- Identify, prioritize, allocate and manage resources to ensure achievement of strategy objectives;
- Provide guidance in the preparation and compilation of regulatory submissions consistent with regulatory policies;
- Interact with regulatory agencies as appropriate to expedite approval or resolve regulatory matters for pending applications;
- Provide leadership, personnel development, training, coaching and mentoring to staff as well as associates in other functional areas;
- Successful integration of personnel and regularory processes of acquired companies (e.g, Megadyne Medical Products, Inc; Torax Medical)

- Operationalize strategy for the global Ethicon business; includes operating in a new business model, collaborating with a non-J&J company, Verb Surgical Inc., in the development of a Digital Surgery (Robotic) Platform

Director, Regulatory Affairs – Energy (2012-2014)

- Served on the Global Management Board and Platform Leadership Team, providing advice, guidance and analysis of critical projects and the global regulatory environment
- Operationalize strategy for the Ethicon Energy business; translate strategic plan to department objectives and goals
- Identify, prioritize, allocate and manage resources to ensure achievement of strategy objectives; Met and exceeded goals for product clearances and approvals across Energy portfolio (e.g., Harmonic ACE+7, Harmonic Focus+, EnSeal Articulating Tissue Sealers)
- Provide guidance to direct reports for the preparation and compilation of regulatory submissions consistent with regulatory policies
- Interact with regulatory agencies as appropriate to expedite approval or resolve regulatory matters for pending applications
- Provide leadership, personnel development, training, coaching and mentoring to staff as well as associates in other functional areas

Group Manager, Regulatory Affairs, 2007-2012

- Successfully led regulatory affairs team throughout product lifecycle for multiple product portfolios: 510(k), PMA (Supplements and Annual Reports), Technical Files and Design Dossiers (CE mark) filings and change determinations, including GMP requirements.
- Accountable for the development and execution of robust global regulatory strategies and plans in order to drive growth; proven record of exceeding schedule for delivery of government registrations/approvals (e.g. first to market Powered Endocutter received clearance in 44 days).
- Successfully promoted five associates within a 2 year timeframe; fostered talent development by presenting stretch assignments as well as other growth opportunities to direct reports; coach/develop direct reports with respect to personal and technical development to support business objectives.
- Led the US RA team in the implementation of the 2010 Medical Device Directive (EU) revisions, ensuring continued compliance to maintain CE marked product and distribution in the European Market without disruption; streamlined process and documentation requirements.
- Regulatory lead and key contributor on the Global Logistics Center(GLC) conversion team; developed strategies to obtain global registrations due to the creation of Ethicon-Endo Surgery, LLC, and sustainment of current global supply/product shipments (largest labeling conversion project in company's history)
- Key contributor to divisional and company Action Teams identifying key areas for improvement; nominated member of the company's Engagement Champion Team to assist teams with low engagement.
- Served on Risk Management Board, providing regulatory risk assessments related to various field issues and input to escalation process (Health Hazard Evaluation and Quality Review Board).
- EES Group Sponsor (2005-2006) and contributing member of the Women's Leadership Initiative (WLI)
- Presenter at Advamed's 510(k) Submissions "101" at the associate level (2004)

Employment History

STEWART ROSE AND ASSOCIATES (Cincinnati, OH) 1998-2001

Senior Research Analyst/Associate

Conducted market feasibility studies for retailers and shopping center developers; responsibilities included demographic analysis and evaluation of economic factors, trade area delineation and market/lifestyle segmentation.

ABBOTT LABORATORIES (Abbott Park, IL) 1989-1998

Senior Regulatory Specialist

Developed strategies and filed IVD International Product Master Files; ensured compliance to import-export regulations. Drafted operating procedures and work instructions for training purposes; Served as the International Regulatory representative on Global Labeling Task Force and IVD Directive Labeling Team.

Product Coordinator, Quality Assurance

Facilitated product development activities to ensure timely market entry of new products and facilitated management reviews. Reviewed/analyzed supporting data to ensure product met specified design goals and package insert claims; served as department reviewer and approver for diagnostic assay manuals and package inserts.

R&D Technician

Developed assays for new and reformulated assays (FMEA and FPIA technologies); performed design testing, analysis, interpretation, organization and presentation of data; Designed test protocols for specific assay development.

UNIVERSITY HOSPITAL (Cincinnati, OH) 1988-1989

Medical Technologist

Performed therapeutic drug monitoring, comprehensive drug screening, and pharmacokinetic studies Instrumentation knowledge includes: HPLC, TLC, GC, Mass Spectroscopy, TDx, and Hitachi Analyzer

Education / Certifications

XAVIER UNIVERSITY – Cincinnati, OH
BSBA Medical Technology

THE CHRIST HOSPITAL – Cincinnati, OH
School of Medical Technology, ASCP Certification received (not renewed)

SIX SIGMA GREEN BELT CERTIFICATION
Ethicon Endo-Surgery (2002)

REGULATORY AFFAIRS PROFESSIONAL SOCIETY
US RAC Certified since 2003

MANAGEMENT FUNDAMENTALS I AND II
LEADERS DEVELOPING LEADERS
Johnson & Johnson

KELLOGG SCHOOL OF MANAGEMENT
Creating and Leading a Culture of Innovation (2011)

SMITH COLLEGE EXECUTIVE EDUCATION
Smith College/Johnson & Johnson: The Leadership Edge (2011)

SMITH-TUCK WOMENS LEADERSHIP PROGRAM (2014)
Global Leaders Program for Women

HARVARD BUSINESS SCHOOL (2015)
Johnson & Johnson: R&D Leadership Program

9.9. CV Of Medical Operations (MO) Evaluator

CURRUCULUM VITAE
Luis Blanco

SUMMARY OF QUALIFICATIONS

Senior Manager for the Medical Operations – Shared Services Group with over 20 years of experience in Johnson & Johnson and has held various Quality Assurance, Quality Systems, Complaint and MDR/MDV Reporting, Compliance, Medical Operations roles of increasing responsibility during his career. Worked at various J&J sites globally including international assignments in the Netherlands, India and China. BS in Metallurgical Engineering from the University of Texas at El Paso and a Masters in Microelectronic Manufacturing Engineering from Rochester Institute of Technology (RIT). Holds a MBA from the University of Texas at El Paso and is a member of American Society for Quality (ASQ), as well as a Certified Quality Auditor (CQA). Core competencies include: Thorough understanding of medical device regulations and requirements for US, EU, Canadian, China, Japan, and other international standards and regulations.

WORK EXPERIENCE

Sr. Manager, Medical Operations

Ethicon and Ethicon Endo-Surgery: **Medical Operations – Shared Services (a Johnson & Johnson Company)** –
July 2017 – Present
Highlight(s):
Central Process Owner for Clinical Evaluation Report Process for Global Surgery (at Johnson & Johnson). Ensures respective CERs for both Ethicon and Ethicon Endo-Surgery products (Existing and New Product Introductions) are compliant to the MedDev Rev. 4 requirements, EU MDR and respective standards and regulations, where applicable.

- Central process owner for the Clinical Evaluation Report process across Global Surgery
- Responsible for the effective optimization and harmonization of CER processes within Global Surgery
- Manages CER processes and linkages within the Quality Systems and Regulatory Processes (e.g. Risk Management, PMS, etc.)
- Manages New Product Development, CFDA and Rest of World CER requirements and documents
- Acts as the CER liaison with respective Notified Bodies and regulatory agencies
- Develops strategies, policies and efficiencies within procedures and processes for current and future regulatory requirements

- Partners with cross-functional business SMEs such as Medical Directors, Post Market Surveillance, Design Quality Engineers, R&D, and
- Regulatory Affairs relating to Performed an Internal Audit on Regulatory Affairs, which included the assessment of Tech File, Design Dossier, Clinical Evaluation Report (CER) Documentation for the Mentor Franchise
- Manages timelines and project deliverables
- Manages the CER staff including project managers, technical and medical writers
- Manages the budget and schedule related to current and projected future CER activities
- Supports CAPA, Audit Observation Failure Investigations, Action Planning and Effectivity Monitoring Activities related to the CER Process

Compliance Manager

Mentor Irving (a Johnson & Johnson Company) – Implants (Class III), Sizers (Class II) and Expanders (Class II) at **Mentor Irving Facility (Texas, USA)** and **Mentor Leiden Facility (The Netherlands)**
January 2016 – Present
Highlight(s):
Recently completed an international assignment at the Mentor Leiden Facility (The Netherlands) in order to prepare the site for Un-Announced Inspections and enhance their Internal Audit Program. The goal was to establish a compliance structure that will be able to manage Un-Announced Inspections and enhance site compliance posture. Currently, stationed at the Mentor Irving Facility performing the Compliance Manager role while continuing to provide compliance support/guidance to the Mentor Leiden facility, where required. Served as the Acting Sr. Compliance Manager from November 2016 to March 2017 for the Mentor Sites.

- Provide compliance education and training (QSR-21CFR Part 820, ISO 13485:2003, Canadian MDR, SOR/98-282, MEDDEV 2.12-1 Rev. 8, European MDD (93/42/EEC as amended by 2007/47/EC and respective Standards and Regulations including Industry Trends) to the Mentor Organization (at Mentor Leiden and Irving Manufacturing Facilities) in support of overall compliance initiatives.
- Leading the Audit Readiness Program and preparation activities for Un-Announced Inspections at Mentor Irving and supporting Mentor Leiden
- Lead the Audit preparation and successful execution of the 2017 BSI 13485/MDSAP Re-Cert Audits at Mentor Irving
- Led the Audit successful preparation and execution of the OCP (Brazil) and TuV ISO 13485 Re-Cert Audits at Mentor Leiden (2016)
- Participate and assist in Internal and External Quality Audits (which include Criss Cross Audits for the Mentor Sites)
- Responsible to establish an Internal Auditor Training Program for the Mentor Leiden Facility - Completed on August and December 2016
- Responsible for the Compliance Metrics and Statistical Trending (Audit Schedule Adherence, Observation, Action Timeliness, Due Date Adherence) for the Site and escalate to CAPA, as applicable.

- Develop, implement, and support Mentor Organization and Corporate Regulatory and Compliance Strategies at Mentor Irving /Leiden
- Support Escalation, CAPA, Field Action and Risk based assessment activities for the Mentor Sites
- Support the adherence and assessments to the J&J MD and Technical Standards
- Lead a Mentor/Ethicon Cross Functional team to update the respective Standards and Regulations listing for the Mentor Franchise in order to improve Tech File, Design Dossier and Risk Management documentation and linkages
- Support New Product Introductions and Development as part of the 4-Corners Project at Mentor Leiden (2016). Worked with R&D/RA/QA/RM Cross functional teams for the development of FDA Submission documentation related to the Mentor Leiden manufacturing process.
- Supported the closure of 2015 ANSM Audit Observations for the Mentor Leiden in compliance to the MEDDEV 2.12-1 Rev. 8 Guidance on Medical Device Vigilance Systems
- Performed an Internal Audit on Regulatory Affairs, which included the assessment of Tech File, Design Dossier, Clinical Evaluation Report (CER) Documentation for the Mentor Franchise.
- Contributed and Participated in Local and Franchise Management Reviews for the Compliance (Internal / External Audit) Section
- Support CAPA, Audit Observation Failure Investigations, Action Planning and Effectivity Monitoring
- Provide guidance with regards to ISO standards, Medical Device Directive (MDD) and FDA regulations, to assess, and verify corrective actions effectiveness. Trend, report, and present results/ recommendations to Mentor Management

Interim ASPAC Regional Compliance Manager

Ethicon (a Johnson & Johnson Company) – Sutures (Class II) and Kitting Products at the **Ethicon Aurangabad** and **Baddi Facilities** and the **Minhang (China) Facility**
November 2014 – December 2015
Highlight(s):
Completed a one (1) year term International assignment as the Regional Compliance Lead for the ASIA Pac area (India and China). The goal was to establish a compliance organization, improve its compliance performance and sustain compliance according to the local, franchise and regulatory requirements. Within the timeframe, the ASIA Pac sites compliance status improved from a RED/RED position to a GREEN/GREEN status based on JJRC reviews and follow-ups. External Inspection performance, Audit metrics and Schedule Adherence were improved. Established an Internal Audit training program to further enhance the skill sets and awareness of the Internal Auditors.

- Provide compliance education and training (QSR-21CFR Part 820/ISO 13485:2003, ISO9001:2008, India D&C Act (Schedule M/Schedule L), WHO/GMP/TRS and respective Standards and Regulations including Industry Trends) to the Ethicon

Organization (for the Asia Pac Facilities in India and China) in support of overall compliance initiatives.

- Lead the efforts for the preparation and adherence to Internal and External Quality Audits and Inspections.
- Established the Internal Auditor Training Program for the Ethicon India Facilities
- Responsible for the Audit Readiness Program for the Asia Pac Facilities in India and China (Ethicon).
- Interface with Notified Bodies (BSI and TuV) and Regulatory (Local FDA) representatives during audits (BSI, Local FDA). Sites achieved excellent compliance audit results at the India and China sites (Ethicon).
- Develop, implement, and support AsiaPac (Ethicon India and China) Organization and Corporate Regulatory and Compliance Strategies
- Provide guidance with regards to ISO standards and FDA regulations, to assess, and verify corrective actions effectiveness. Trend, report, and present results/ recommendations to management
- Responsible for managing and improving the Compliance culture and metrics for the AsiaPac facilities
- Core Member of the MD&D (Multi- Op Cos) Audit Readiness Initiative 2013, 2014 and 2015.
- Leading Sub-Team (MD Op Cos) for the Risk Score Team under the MD&D Audit Readiness Initiative 2013, 2014 and 2015.
- Lead the MD Op Cos Sub-team regarding Internal Auditor Qualifications and Training requirements to be deployed across the MD level.
- Responsible for the Compliance Metrics and Trending (Audit Schedule Adherence, Observation and Action Timeliness, Due Date Adherence) for the Site
- Supported Escalation, CAPA, Field Action and Risk based assessment activities for the Mentor Site
- Support CAPA, Audit Observation Failure Investigations, Action Planning and Effectivity Monitoring
- Contributed and Participated in Local and Franchise Management Reviews for the Compliance (Internal / External Audit) Section
- Support the adherence and assessments to the J&J MD and Technical Standards
- Site Deployment Team Member for the India Sites (Aurangabad and Baddi) for the ADAPTIV project (Document Change, MVI and Change Project)

<u>Quality Systems and Compliance Systems Manager</u>

Mentor Texas (a Johnson & Johnson Company) – Implants (Class III), Sizers (Class II) and Expanders (Class II) at **Mentor Irving Facility and Distribution Center – Coppell, Texas**
March 2013 – December 2014
Highlight(s):
As the QS and Compliance Manager for the Mentor Irving site, the goal was to develop the QS and Compliance organization, improve its Quality Systems (by deploying EtQ Audit and ADAPTIV), Compliance performance and sustain compliance according to the local, Franchise and Regulatory

requirements in a highly regulated environment. During this period, the Mentor Irving site was able to achieve excellent External Inspection performance (2 FDA, 2 BSI and OCP Audits with Zero Observations). Audit metrics and Schedule Adherence were improved. Established Internal Audit training program and auditor council to further enhance the skill sets and awareness of the Internal Auditors for the Mentor site.

- Provide compliance education and training (QSR-21CFR Part 820, ISO 13485:2003, Canadian MDR, SOR/98-282, European MDD (93/42/EEC as amended by 2007/47/EC and respective Standards and Regulations including Industry Trends) to the Mentor Organization (at Irving, Texas Manufacturing Facility and Coppell, Texas Distribution facility) in support of overall compliance initiatives.
- Lead guidance and preparation for the FDA Inspections at Mentor Irving in July 2013 and May 2014 – Zero Non-Conformances
- Lead guidance and preparation for the BSI Re-Cert and Surveillance Audits at Mentor Irving in October 2013 and May 2014 – Zero Non-Conformances
- Lead guidance and preparation for the OCP (Brazilian) Audit at Mentor Irving May 2014 – Zero Non-Conformances
- Lead guidance and preparation for the BSI Tech File Audit for Mentor Santa Barbara Audit – 4 Minor Non-Conformances for Santa Barbara Franchise
- Established and Lead Trainer for the Internal Auditor Training Program for the Ethicon San Lorenzo Facility - Nov 2013 and Mentor Irving Facility - Mar 2014
- Responsible for the Audit Readiness Program for Mentor Irving Facility and Distribution Center at Coppell, Texas
- Interface with Notified Bodies (BSI) and Regulatory (FDA) representatives during audits (BSI, FDA, OCP and PMDA).
- Supported the External Audits for Ethicon San Angelo Facility (Co-Backroom Lead and Front Room Scribe) for PMDA Audit (February 2014) and JJRC Audit (June 2014).
- Leading Sub-Team (Multi-Op Cos) for the Risk Score Team under the MD&D Audit Readiness Initiative 2013 and 2013 YTD
- Management the Document Control and Training groups for the Mentor Irving Site.
- Responsible for the Compliance Metrics and Statistical Trending (Audit Schedule Adherence, Observation, Action Timeliness, Due Date Adherence) for the Site and escalate to CAPA, as applicable.
- Supported Escalation, CAPA and Field Action activities for the Site
- Contributed and Participated in Local Management Reviews for the Compliance (Internal / External Audit) Section
- Support CAPA, Audit Observation Failure Investigations, Action Planning and Effectivity Monitoring
- Supported the Mentor Irving in compliance to the MEDDEV 2.12-1 Rev. 8 Guidance on Medical Device Vigilance Systems
- Business Partner and Site Deployment Core Team Member for the Mentor Irving for the ADAPTIV project (Document Change, MVI and Change Project)

Quality Systems and Compliance Systems Manager

Ethicon (a Johnson & Johnson Company) – Suture (Cobalt, Split-Flow and Specialties – Class II) and Catheter (Class III)
Business Units - **Ciudad Juarez, Chihuahua, Mexico at the Torres and Independencia Facilities**
June 2009 – March 2013
Highlight(s):
As the Compliance Manager for the sites, lead the compliance program that resulted in excellent External Inspection performance (BSI and ANVISA Audits with Zero Observations). Co-Lead the Ethicon Franchise Worldwide deployment of Do it Right.

- Provide compliance education (QSR-21CFR Part 820, ISO 13485:2003, Canadian MDR, SOR/98-282, European MDD (93/42/EEC as amended by 2007/47/EC and respective Standards and Regulations including Industry Trends) to the Juarez Organization (at Ethicon Torres and Independencia facilities) in support of overall compliance initiatives, including support of Ethicon LLC BSI/ISO Certification initiative.
- Successfully deployed and obtained ISO 13485:2003 Certification for the Ethicon Juarez facilities (Torres and Independencia)
- Lead guidance and preparation for the ANVISA Regulation and Audit – Zero Non-Conformances
- Lead the Organization in achieving successful external inspection results. Develop, implement, and maintenance of the Inspection Readiness process. Coordinate and report inspection schedules and progress. ISO 13485:2003 Re-Certification – Zero NCs. ANVISA Audit – Zero NCs.
- Participate and assist in Internal and External Quality Audits (which include Corp. Ethicon and Criss Cross Audits for the Juarez Torres and Independencia Facilities and other Ethicon Sites).
- Interface with Notified Bodies (BSI) and Regulatory (FDA) representatives during audits (Juarez – BSI 2009/2010/2011/2012 and San Angelo –FDA January 2010
- Responsible for the Ethicon Juarez FDA Audit Readiness Program.
- Provide guidance with regards to ISO standards and FDA regulations, to assess, and verify corrective actions effectiveness. Trend, report, and present results/ recommendations to facility management
- Responsible for the Internal Audit Program Adherence and activities
- Responsible for the Compliance Metrics and Statistical Trending (Audit Schedule Adherence, Observation, Action Timeliness, Due Date Adherence) for the Site and escalate to CAPA, as applicable.
- Supported Escalation, CAPA and Field Action activities for the Site
- Support CAPA, Audit Observation Failure Investigations, Action Planning and Effectivity Monitoring
- Support Customs Import / Export adherence activities from a Compliance perspective (including Site FDA Customs Reviews at El Paso J&J Warehouse)
- Lead Site Assessments and Training for Combination Products for the Ethicon Juarez.
- Lead the Local Management Reviews for the Ethicon Juarez Sites (including inputs to Internal and External Audit performance)

- Responsible for the Operator Certification Program for the Ethicon Juarez Operations. Now a benchmark for the J&J Juarez Campus
- Co-Lead for the Deployment of the Do It Right/HER Initiative for the Ethicon Franchise
- Business Partner and Site Deployment Lead for the Ethicon Juarez Operations for the ADAPTIV project
- Acting Quality Systems Compliance Leader for the San Angelo Facility from October 2009 to February 2010. Completed the 2009 Internal Audit Schedule on time and Lead the FDA Readiness Activities for the FDA Audit in San Angelo on January 2010 with Zero NCs.
- Acting Quality Operations Leader for the Ethicon Juarez Operations from September 2011 to September 2012. Supported the Thermachoice, Cobalt, D-Specials and E-Pack processes during this time frame.

Worldwide Customer Quality (WCQ) Manager

Ethicon (a Johnson & Johnson Company) – **Somerville, New Jersey**
Feb 2006 – June 2009
Highlight(s):
As the WW Complaint Manager for Ethicon, lead the Complaint Handling and Vigilance Reporting Groups in Somerville, New Jersey and the respective Complaint Handling units across France, Scotland, Brazil, Germany and Switzerland. Successful FDA inspections were achieved with no 483s from February 2006 – June 2009 in the Complaint Handling Process. Deployed eMDR application for the Ethicon Franchise.

- Global Process Owner of the Complaint Management System Application (Remetrex)
- Lead Oversight of Ethicon Complaint Handling Units Worldwide (France, Switzerland, Germany, Brazil, Scotland) and Partnered with JJKK, JJ Canada and Australian Affiliates.
- Reduce regulatory exposure through increase efficacy in management of product complaints by improvement in multiple complaint process metrics Accountable for department compliance with all Food & Drug Administration (FDA) and European Union Medical Device Directives (MDD) regulations governing adverse event reports such as Medical Device Reports (MDR) and Medical Device Vigilance (MDV).
- Provide compliance education (QSR-21CFR Part 820/QSR-21 CFR Part 803/ISO 13485:2003 including Industry Trends) with regards to the Product Complaint Handling Process to the Ethicon Organization (including global facilities and functions) in support of overall compliance and product complaint handling initiatives
- Participates and assists in Internal and External Quality Audits (which include Corp. Ethicon and Q&CWW)
- Interface with Notified Bodies (BSI) and Regulatory (FDA) representatives during audits at Corporate and Manufacturing Sites (Juarez Plant – May 2008, San Lorenzo Plant – August 2008 and Neuchatel Plant August 2008).
- Responsible for the Complaint Metrics and Statistical Trending (Complaint Timeliness, Complaint Codes, MDR/MDV Reporting) for the Ethicon Franchise and escalate to CAPA, as applicable.
- Supported Escalation, CAPA and Field Action activities for the Site.

- Support CAPA, Audit Observation Failure Investigations and Complaint Investigations for the Ethicon sites.
- Contributed and Participated in Local Site(s) and Franchise Management Reviews for the Complaint Handling and Vigilance Reporting Section
- Coordinates the communication of MDR complaints with FDA and MDV for product complaints with the Competent Authorities (MHRA, Swiss Medic), Authorized Representatives and Regulatory Franchise Managers, as applicable.
- Oversight of the FDA quarterly reports (ASR) and managed requests and responses from Competent Authorities such as MHRA, Swiss Medic related to complaint files and MDR/MDV reporting.
- Supported Device Registries and Clinical Trials that feed into the Complaint Handling process and Medical Device Reporting processes for Ethicon Franchise
- Supported Post Market Surveillance and Risk Management Activities and Initiatives and partnered with IM to deploy a data extraction database for complaint handling and post market surveillance reports and trending.

Compliance Systems Leader

Ethicon (a Johnson & Johnson Company) – Suture and Gynecare Business Units
Ciudad Juarez, Chihuahua, Mexico at the Torres and Salvarcar Facilities
May 2002 – Feb 2006

- Provide compliance education (QSR-21CFR Part 820/ISO 13485:2003 including Industry Trends) to the Juarez Organization (at Ethicon Torres and Salvarcar facilities) in support of overall compliance initiatives
- Lead guidance, preparation and Audit Co-Host for the FDA Inspection at Ethicon Juarez (June 2004) – One (1) Minor Non-Conformance
- Lead the FDA Response Action and Documentation for the June 2004 Audit.
- Successfully deployed and obtained ISO 13485:2003 Certification for the Ethicon Juarez facilities (Torres and Salvarcar)
- Participate and assist in Internal and External Quality Audits (which include Corp. Ethicon and QCS for the Juarez Torres and Salvarcar facilities
- Interface with Notified Bodies (BSI) and Regulatory (FDA) representatives during audits
- Supported the CAPA activities and assessments for the Site
- Management the Document Control and Quality Systems groups for the Ethicon Juarez Sites.

Interim Plant Quality Manager

Ethicon (a Johnson & Johnson Company) – Suture and Gynecare Business Units
Ciudad Juarez, Chihuahua, Mexico at the Torres and Salvarcar Facilities
Jan 2005 – July 2005

- Ensure compliance to the QSR/ISO requirements for the Juarez Facilities
- Established and operate within an effective budget and manpower plan for the QA Organization.

- Served as a Management Representative for the Juarez Facilities

Supply Chain Leader

Ethicon (a Johnson & Johnson Company) – Sutures and Gynecare Business Units - **Ciudad Juarez, Chihuahua, Mexico**
May 2001 - May 2002

- Supervised and Coordinate New Hire Training and Development for the Juarez Quality Systems Engineers and Technicians for the Gynecare Product Line
- Responsible for reviewing and approving all Quality Assurance test methods and inspections procedures of raw material, work in progress and finished product.
- Acted as plant management deputy during corporate internal audits and any plant regulatory inspection.

Sr. Quality Systems Engineer

Ethicon Endo-Surgery (a Johnson & Johnson Company) – Ligation/Hand-Held/Open Manufacturing (Lubrication and Staple Making) and Raw Material Inspection (RMI) - Business Units - **Ciudad Juarez, Chihuahua, Mexico**
May 1999 – May 2001

- Supervised and Coordinate New Hire Training and Development for the Juarez Quality Systems Engineers
- Co-Lead guidance and preparation for the FDA Inspection at Ethicon Endo-Surgery – One (1) Minor Non-Conformance
- Managed the Communications Room for Corporate, ISO/GMP and FDA audits for the Juarez facility

Quality Systems Engineer

Ethicon Endo-Surgery (a Johnson & Johnson Company) – Access (Trocars)/Ligation/Endo Stapler and Cutter/Breast Care Business Units - **Ciudad Juarez, Chihuahua, Mexico**
April 1996 – May 1999

- Supervised Eight Quality Systems Technicians for both 1st and 2nd Shift Operations
- Coordinated the Internal Audit Program for the Ethicon Endo-Surgery Juarez facility
- Provided technical support for Operational and Performance validations and product transfers (Ligation and Breast Care Business Units)

Automated Wet Stations (AWS) Process Engineer

Intel Corporation - Components Manufacturing Group - **Rio Rancho, New Mexico**
July 1994 - April 1996

- Resolved Manufacturing Wet Etch/Clean Process and Technology Issues
- Assisted in the development of the Backend processes at Intel's Development Site (Portland, Oregon) for the Pentium Processor (125-175 MHz) chip set.

Surface Mount (SMT) Process Engineer

Rockwell International - Telecommunications Division - **El Paso, Texas**
May 1993 - June 1994

- Responsible for Process Support and Development of Surface Mount Operations for products such as PCMCIA's, GPS units, Automotive Electronics and Modems.
- Implemented Manufacturing Process Improvements and Enhancements

Process Development Engineer

IBM Corporation - Advanced Semiconductor Technology Center - **East Fishkill, New York**
February 1991 - March 1993

- Resolved Manufacturing Wet Etch/Clean and Thin Films Process and Technology Issues
- Assisted in the development of the Backend processes at IBM's Development Site (East Fishkill, New York) for the 64 Meg DRAM chip set.

EDUCATION

Masters in Business Administration (MBA)
The University of Texas at El Paso (El Paso, Texas)
Date of Graduation: May 2001

Masters of Engineering in Microelectronics Manufacturing Engineering
Rochester Institute of Technology (Rochester, New York)
Date of Graduation: August 1992

Bachelor of Science in Metallurgical Engineering
The University of Texas at El Paso (El Paso, Texas)
Date of Graduation: December 1990

CERTIFICATIONS/TRAINING/MEMBERSHIPS

- CQA Certified Auditor (ASQ – June 2009 – June 2018)
- Attended JJRC Auditor Training (July 2014)
- MD&D Supply Chain Compliance Education Audit Training (January 2014)
- Management Fundamentals I (Johnson &Johnson 2006)
- Black Belt Trained (EES- Johnson & Johnson Process Excellence - August 1999)
- Certificate in Management (Sponsored by AMA-1998)
- Certificate of Supervision (Sponsored by AMA-1997)

SKILLS

Knowledge of Medical Device and Quality System Regulation such as 21 CFR Part 820 and 803 Regulations, ISO 13485:2003, ISO 9001:2008, India D&C Act (Schedule M/Schedule L), WHO/GMP/TRS, ANVISA RDC 16/2013, Japan MHLW Ministerial Ordinance No.169, 2004, Australian Therapeutic Goods (Medical Devices) Regulations 2002, China Medical Device Regulation, Canadian MDR SOR/98-282, MEDDEV 2.12.1 Rev. 8, European MDD (93/42/EEC as amended by 2007/47/EC, MEDDEV 2.7.1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies plus respective Standards and Regulation (Rev. 4) and the New EU MDR. Background in statistical methods and tools (SPC, Minitab). Trained in Six Sigma (Process Excellence and Lean Tools). Knowledge of Office Windows (Excel/Word/Visio and Powerpoint).

REFERENCES

Furnished Upon Request

9.10. CER Revision History

Revision history for CER (# SCN070740, A)

Revision Number	Date (DD Month YYYY)	Description of Change
1	17 December 2019	Initial release.

9.11. CER Approval Signatures (E-Signatures)

Medical Affairs Evaluator

Approver Name/Title	Signature
Raymond Fryrear, II, MD VP Integrated Leader, EN EM TOR	Raymond Fryrear II Digitally signed by Raymond Fryrear II DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1070504, cn=Raymond Fryrear II Reason: I attest to the accuracy and integrity of this document. Date: 2019.12.17 21:47:22 -05'00'

Regulatory Affairs Evaluator

Approver Name/Title	Signature
Kim Shoemaker Sr. Director, Global Regulatory Affairs, Ethicon	M KIMBERLY SHOEMAKER Digitally signed by M KIMBERLY SHOEMAKER DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=174307, cn=M KIMBERLY SHOEMAKER Reason: I am approving this document. Date: 2019.12.18 12:17:43 -05'00' Adobe Acrobat version: 11.0.20

Medical Operations Evaluator / CER Author

Approver Name/Title	Signature
Luis Blanco Senior Manager Medical Operations	LUIS BLANCO Digitally signed by LUIS BLANCO DN: c=US, o=JNJ, ou=Subscribers, cn=LUIS BLANCO, 0.9.2342.19200300.100.1.1=31482 Reason: I am approving this document. Date: 2019.12.18 10:36:00 -07'00' Adobe Acrobat version: 11.0.20

Reference CER Attachment <number> for Declaration of Interest (DOI) Forms for CER Evaluators