

1. PURPOSE

The purpose of this procedure is to establish the process for documenting, evaluating, and investigating complaints to determine (as required) corrective actions, field corrections, medical device reporting (MDR), and product retrieval (recall). This procedure establishes reporting methods and timelines consistent with FDA guidelines.

This procedure also establishes the responsibilities of GT Medical and the contract manufacturer, IsoRay, within the complaint process.

2. SCOPE

This procedure applies to all customer feedback received by GT Medical.

3. REFERENCES

- Food and Drug Administration Code of Federal Regulations 21 CFR Part 803 – “Medical Device Reporting”
- Food and Drug Administration Code of Federal Regulations 21 CFR Part 806 - “Medical Devices; Reports of Corrections and Withdrawals”
- Medical Device Reporting for Manufacturers - Guidance for Industry and Food and Drug Administration Staff
- 21 CFR part 7, Subpart C “Recalls”
- 45 CFR part 164.502(b), Minimum Necessary Standard
- FDA Form 3500A Mandatory Medwatch Reporting
- SOP-001, Quality Manual
- SOP-002, Purchasing and Supplier Controls
- F-002F, Supplier Corrective Action Request (SCAR)
- F-003A, Complaint Handling Form
- F-003B, Complaint / Feedback Log

4. DEFINITIONS

- 4.1. Complaint: Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after it is released for distribution.
- 4.2. Designee: Personnel given responsibility for one or more aspects of complaint processing. Designees will be competent (through training or other means) to perform their responsibilities.
- 4.3. General Feedback: Any customer feedback that does not meet the definition of a complaint.
- 4.4. Protected Health Information (PHI): individually identifying health information, including demographic information, in any form or medium (electronic, paper, verbal, etc.) (excludes, employment records, individuals deceased 50+ years, etc.). Reference 45 CFR 160.103.
- 4.5. Reportable Event: The adverse events or problems that the medical device regulations require to be reported. Under 21 CFR Part 803 or 806A, a report must be submitted to the FDA whenever the manufacturer becomes aware of information that reasonably suggests that one of its devices:

- May have **caused or contributed** to a death or a serious deterioration in the state of health or serious injury, or
- Has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a death or a serious deterioration in the state of health or serious injury, or
- A device which shows no malfunction or deterioration, but nevertheless has a characteristic which is likely to cause or contribute to a death or a serious deterioration in the state of health or serious injury (example: omissions or inaccuracies in the instructions leaflet), should be reported as a near incident.

4.6. Serious deterioration of health / injury: The adverse event in which any one of the following occurs:

- Life threatening illness / injury;
- Injuries or illness that result in permanent damage to a body structure or permanent impairment of a body function;
- A condition necessitating medical or surgical to prevent the above conditions;
- Any indirect harm as a consequence of an incorrect diagnosis or IVD test results when used within the manufacturer instruction for use; or
- Fetal distress, fetal death or congenital abnormality or birth defects

5. RESPONSIBILITY

5.1. Any employee of GT Medical who receives or otherwise becomes aware of information that a complaint or potential MDR reportable event has occurred is responsible for notifying Operations or designee within 24 hours so that complaint documentation and evaluation may be initiated.

5.2. The responsibilities of GT Medical and IsoRay for particular aspects of the complaint process are outlined in the sections below.

5.3. The RAQA consultant is responsible to act on behalf of GT Medical for submitting eMDR¹.

5.4. *Operations will review and process general feedback and complaints.*

6. PROCEDURE

6.1. **Receipt of Customer Feedback** (Section 1, F-003A Complaint Handling Form)

6.1.1. Classification of Feedback: Feedback shall be classified per the definitions given in Section 4 of this procedure to determine Logging and Documentation requirements.

6.1.1.1. Feedback meeting the definition of a product **complaint** will be processed in accordance with the remainder of this SOP.

6.1.1.2. Feedback meeting the definition of General feedback, only required documentation in the F-003B 'General feedback' tab and will be reviewed by Operations.

¹ Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, GT Medical, has authorized Lean RAQA Systems to submit in the Electronic Submissions Gateway on its behalf.

Guidelines for what are typically considered complaints:

- When a customer verbally complains or sends a letter or email to a GT Medical employee based upon the unacceptability of a GT Medical product for any of the identified reasons noted in the definition of a complaint.
- When an Adverse Event is reported to any GT Medical employee.
- When the customer perceives a trend of failures occurring with the unit and expresses unacceptability of this trend as it relates to any of the identified reasons noted in the definition of a complaint.
- When the product does not operate according to the instructions for use, assuming existence of apparent malfunction.

6.1.2. Complaint Documentation: When feedback is classified as a complaint, Operations shall initiate Sections 1 (General Information) of F-003A, Complaint Handling Form. If more information is necessary, Operations will follow-up with the complainant.

6.1.3. Complaint / Feedback Log: Complaints and feedback shall be recorded in F-003B, on their respective tab. Complaints are numbered consecutively (beginning with 1). General feedback is organized by date and customer.

6.1.4. Confidentiality: If any of the customer feedback received contains personal information, the complaint records shall be kept confidential to the extent required by law.

6.2. **Complaint Evaluation** (Section 2, F-003A Complaint Handling Form)

6.2.1. Documentation: Operations will document evaluation of the complaint with consideration for it type, reportability, and investigation requirements in Section 2 of F-003A, Complaint Handling Form.

6.2.2. Reportability: Complete the flow chart, to determine if the complaint must be reported. This must be performed within 10 days of receiving the complaint and within 2 days for complaints that could require remedial action to prevent public risk. When in doubt, there should be a pre-disposition to report rather than not to report. See reporting criteria below. **Appendix B provides a summary of the MDR reporting timelines for the FDA for medical devices. If a complaint is determined to be reportable, see Section 6.7 for additional information on the reporting process.**

6.2.2.1. MDR actions: Appendix B provides a summary of the MDR reporting actions and timelines for the FDA.

6.2.2.2. Reporting criteria: Any incident involving a device which meets the three basic reporting criteria listed below is considered as an adverse incident and should be reported to the FDA:

- An event has occurred.
- The manufacturer's device is associated with the event.
- The event led, or might have led, to one of the following outcomes: to a death of a patient, user or other person or serious deterioration in the state of health of a patient, user or other person.
 - Serious deterioration in state of health can include:

- Life-threatening illness or injury;
- Injuries or illnesses that result in permanent impairment of a body function or permanent damage to a body structure;
- A condition necessitating medical or surgical intervention to prevent the above conditions;
- Any indirect harm as a consequence of an incorrect diagnosis or IVD test results when used in accordance with the manufacturer's instructions for use; and/or
- Fetal distress, fetal death or congenital abnormality or birth defects.

Note: For a near incident to be reported, a possible direct link with the device, or with shortcomings in the information supplied, should be clearly established.

6.2.2.3. Special considerations:

- Those adverse incidents involving particular issues of significant public health concern as determined by the FDA should be reported regardless of exemption criteria.
- Similarly, those adverse incidents, which are subject to an exemption become reportable to the FDA if a change in trend (usually an increase in frequency) or pattern is identified.
- The same considerations apply to a FDA's decision whether to inform a manufacturer of an incident reported via a User Reporting or other system.
- Utilize Appendix B to determine reporting time and type of report required for each type of event that has a reportable incident.

6.2.3. Complaint / Feedback Log: The F-003B, Complaint / Feedback Log will be reviewed for other relevant or similar events that indicate adverse trends. This information is also useful in determination of reportability and/or investigation requirements.

6.2.4. Investigation Determination: All device complaints shall be investigated as per 21 CFR Part 820.198, unless an investigation was already performed for a similar complaint or the issue regarded in the complaint is being addressed per a supplier corrective action (SOP-002, Purchasing and Supplier Controls).

NOTE: If no investigation is to be performed, document the justification and the person making the determination on the F-003A, Complaint Handling Form.

6.3. **Device Complaint Investigation** (Section 3, F-003A Complaint Handling Form)

6.3.1. Overview: If an investigation is required, Operations will forward the complaint form to IsoRay (the contract manufacturer) for investigation. The activities and results of the Complaint Investigation shall be documented in Section 2 of the F-003A, Complaint Handling Form for GT Medical's evaluation. IsoRay shall determine root cause and whether or not the product conformed to specifications.

6.3.2. Risk Management: IsoRay shall update its risk management documentation, as appropriate, depending on the results of the investigation.

6.3.3. Containment: IsoRay shall take appropriate containment actions for nonconforming or potentially nonconforming product. In the case where the product has been released to the customer, GT Medical shall be notified immediately (same day). GT Medical shall take appropriate containment actions, including recall, as necessary.

6.4. **Supplier Corrective Actions** (Section 4, F-003A Complaint Handling Form)

6.4.1. Overview: Action in response to a complaint due to nonconforming product shall be proportionate to the effect(s), or potential effect(s) of the nonconformity. Most commonly this is covered by supplier notification, and as applicable, supplier corrective action. If GT Medical determines from the investigation that corrective or preventive actions are required to resolve a complaint, the procedure SOP-002, Purchasing and Supplier Controls shall be followed to request corrective/preventive action. Documentation of supplier corrective action per SOP-002 is required if the complaint occurred as a result of a nonconformance related to product safety or efficacy. If IsoRay has already initiated corrective or preventive action as a result of the investigation, a SCAR is not required (as long as a reference to IsoRay's CA/PA is documented in the Complaint Handling Form).

6.5. **Closure of Device Complaint** (Section 5, F-003A Complaint Handling Form)

6.5.1. Overview: Upon resolution of the complaint, the Quality Representative or delegate shall sign and close complaint on the F-003A, Complaint Handling Form.

Note: A complaint can be closed even if a related SCAR is still opened as long as the actions to resolve the complaint are planned and are taken into the SCAR process as per SOP-002, Purchasing and Supplier Controls.

6.6. **Trending of Complaints**

Information from complaints shall be collected, trended, and reported in the Management Review Meeting per SOP-001, Quality Manual. If analysis reveals an adverse trend, the information shall be forwarded for possible action with the contract manufacturer per SOP-002, Purchasing and Supplier Controls.

6.7. **Process for FDA Reporting of Complaints**

6.7.1. Reportable Events: If the event is determined to be reportable, GT Medical will inform the RAQA consultant and the RAQA consultant will take the following steps:

- 6.7.1.1. If the event requires reporting to FDA, Medical Device Reports will be completed and submitted electronically using the FDA's eSubmitter tool and the Electronic Submissions Gateway (ESG).
 - The eSubmitter is a tool that enables entities to prepare and complete MDR information in an electronic format using the FDA MedWatch Form 3500A.
 - The ESG is an FDA-wide solution for accepting electronic regulatory submissions such as electronic MDRs (eMDRs). Once electronic MDRs are prepared and completed using the eSubmitter tool, these are submitted to the FDA's CDRH using the ESG.

- 6.7.1.2. To prepare and complete a new eMDR, open the eSubmitter tool, click on “Create New Submission” and then select the “CDRH: MedWatch Form 3500A (OMB No. 0910-0291)” submission type.
- 6.7.1.3. Enter the following details relating to the eMDR.
- Descriptive Name: The descriptive name is for internal use and is used for distinguishing one eMDR from another. This name shall be the same as the Manufacturer (MFR) Report Number described below.
 - File Name: The file name represents the name used to store the eMDR file within the file system and is also used for distinguishing one eMDR from another. The file name shall also be the same as the MFR Report Number described below.
 - Additional Comments: Enter comments that further describe the eMDR beyond the descriptive name. The comments are optional and are intended for internal use.
 - Manufacturer (MFR) Report Number: This is a unique identifier used for each individual eMDR. The eMDR shall consist of the 10-digit facility registration number, followed by a 4-digit year, followed by a 5-digit sequence number.
 - Considering the following example for GT Medical, the file names for the first two eMDRs submitted in year 2017 would be XXXXXXXXXXXX-2017-00001 and XXXXXXXXXXXX-2017-00002.
- 6.7.1.4. Complete FDA Form 3500A following the instructions available in the following website:
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM295636.pdf>
- 6.7.1.5. Attach or refer to any supporting files or legal disclaimers as required.
- 6.7.1.6. Once FDA Form 3500A is complete with all the required fields, click on “Package Files” on the top toolbar of the eSubmitter tool.
- 6.7.1.7. After the eMDR submission is packaged, the file is saved in the selected file directory or path.
- 6.7.1.8. Log in to the ESG using the Web Trader Account information, click on “Send Document”, enter the packaged eMDR file path or directory, select the appropriate signing certificate and then submit the eMDR to CDRH.
- 6.7.1.9. GT Medical shall receive three (3) acknowledgements after the eMDR is submitted to the FDA using the ESG:
- Acknowledgement 1: The first acknowledgement confirms that the eMDR submission was successfully received by the ESG. If this acknowledgement is not received, contact the ESG helpdesk for support.

- Acknowledgement 2: The second acknowledgement indicates the eMDR submission successfully reached CDRH. If this acknowledgement is not received, contact the ESG helpdesk for support.
- Acknowledgment 3: The third acknowledgement indicates whether the eMDR submission was successfully loaded or if any errors occurred during validation and loading. If an error message is received in Acknowledgment 3, correct the errors and resubmit the eMDR following the electronic submission instructions in this procedure,

- 6.7.1.10. The eMDR must be submitted to the FDA in the required timeframe as listed in Appendix B of this procedure.
- 6.7.1.11. The FDA considers the receipt date for an eMDR to be the date the eMDR arrived at the ESG (Acknowledgment 1), but only if the eMDR is successfully validated and loaded in the CDRH database (Acknowledgment 3 with no error message). If a failure occurs during the validation or loading process (Acknowledgment 3), the error(s) described in the third acknowledgment need to be corrected and then the eMDR resubmitted. If the resubmitted eMDR is successfully loaded, (Acknowledgment 3 with no error message), the receipt date will be the date that the resubmitted eMDR arrived at the ESG, as documented in Acknowledgment 1 for the resubmitted eMDR.
- 6.7.1.12. If the device was manufactured at a site other than where the original Complaint Files are maintained, a copy of the complaint will be sent to the manufacturer.
- 6.7.1.13. Subsequent Reports will be issued if required. In the case of an MDR, a supplemental report is issued to the FDA if additional material information becomes available after the initial report has been submitted or upon request for additional information by the FDA.
- 6.7.1.14. Any supplemental, follow-up or additional information report submissions shall also be prepared, completed and submitted in an electronic format using eSubmitter and ESG as described for eMDRs in this procedure.
- 6.7.1.15. A paper copy of all eMDR records and supporting documents (including all electronic acknowledgments sent by FDA in response to such eMDRs) must be filed and controlled in accordance with Document and Record Controls as per SOP-100, Quality Manual. Complaint requiring MDR will be maintained in a specially designated area or be uniquely identified (e.g. a red folder).
- 6.7.1.16. Closure of the MDR: Closure of an MDR incident shall be based on the results of the investigation and/or receipt of a closeout report from the FDA.

6.8. Reporting events to notified bodies

- 6.8.1. GT Medical shall report adverse events to notified bodies, and other applicable regulatory authorities, in accordance with the specific requirements of those authorities provided to industry.

6.9. Recalls

6.9.1. Requirements for reporting: Should the evidence point to the need for a medical device recall, specific reporting action is required by all applicable Regulatory Bodies.

6.9.2. Responsibility for Recalls: The manufacturer whose name appears on the label is responsible for all recall communications to end users and the FDA. GT Medical will notify its distributors when and if any information becomes available that would suggest that product sold to them might require a recall.

6.9.3. Complaint initiated Recalls: Whenever GT Medical is made aware of customer complaints involving product malfunction or serious injury, an investigation shall begin immediately. If the investigation confirms product is defective and malfunctioning, a Health Hazard Evaluation, per *21 CFR, Part 7.41, Health hazard evaluation and recall classification*, shall be conducted by GT Medical. All products remaining undistributed at GT Medical is to be immediately quarantined.

6.9.4. Recall Strategy: A recall strategy must then be identified taking into consideration the following factors:

- Results of health hazard evaluation
- Ease in identifying the product
- Degree to which the deficiency is obvious to user
- Degree to which the product remains unused
- Continued availability of essential product

6.9.5. The recall strategy should address the following issues per *21 CFR, Part 7.42, Recall Strategy*:

- Depth of the recall
- The recall communication to notify the user which should contain the following:
 - Product name
 - Lot number
 - Part number
 - Unique Device Identifier (UDI) that appears on the device label or on the device package
 - The reason for the recall and the hazard involved
 - Specific instructions on what to do
 - Enclose a means for the user to report to the recalling firm whether it has any of the products (i.e. postcard, fax number, telephone number, etc.)

6.9.6. In the event of a field action, order traceability is maintained throughout the duration of the product's life by linking the GT Medical order number with the contract manufacturer's order number in the order management software.

6.9.7. Recall Effectiveness Check: The means to verify that all consignees have received notification (registered mailing) and the level of effectiveness checks that have been conducted (second mailing, telephone call). Refer to "*Methods for Conducting Recall Effectiveness Checks*" – FDA, June 16, 1978.

6.9.8. Communicating with the FDA: The FDA is to be notified and the following information supplied:

- Copy of Customer Notification Letter
- Copy of Instructions for Use (IFU)
- Device labels, all levels (Current and those to be used for reconditioning, if applicable)
- Official *21 CFR 806.10* Report and Health/Risk Assessment per *21 CFR 7.41*
- Distribution List
- Items stated as required in FDA Guidance *“Documents and Information Required by FDA for Device Recall/Field Corrections”*
- Health Hazard Evaluation (HHE) Form
- This form can be obtained from the following website:
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/UCM126211.doc>

6.9.9. Recall status reports are to be prepared and given to the FDA every two or four weeks. The report shall contain the following:

- Number of consignees notified, the date notified, and the method of notification
- Number of consignees responding to the recall communication and quantity of products on hand
- Number of products returned or corrected by each consignee and the quantity of product accounted for
- Number and result of effectiveness checks made
- Estimated time frame for completion of recall
- Disposition of inventory

6.9.10. The recall can be terminated upon receipt of notification from the FDA. Formal request to FDA for Recall Termination can be made as appropriate.

6.9.11. All FDA recall records and related documentation shall be filed and maintained per Document and Record Controls established in SOP-001, Quality Manual.

6.9.12. Recalls initiated from other Quality Issues: In the event GT Medical becomes aware of quality issues not directly associated with complaint information (i.e. – NCR's, vendor notifications, etc.) and needs to make corrections to product in the field, GT Medical will open a complaint using form F-003A, Complaint Handling Form to document the investigation. GT Medical will then use the Health Hazard Evaluation (HHE) Form² to evaluate the need to report actions to the regulatory authorities. GT Medical will use F-003A, Complaint Handling Form to explain events leading to the consideration of action on product in distribution, summarize the HHE results, and conclusions regarding the need to report the action to the FDA per the above procedure. Should GT Medical determine the

² This form can be obtained from the following website:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/UCM126211.doc>

issue does not require reporting, a record of the investigation and justification will be maintained in the complaint record.

7. QUALITY RECORDS (REPORTING AND RECALLS)

7.1. The following information must be retained in the appropriate file:

- A copy of the original complaint record and/or non-conformance report.
- Documentation of follow-up and attempts to follow-up and obtain additional information about the event.
- An explanation of why certain information cannot be obtained.
- Copies of any relevant test reports and investigation reports.
- Documentation related to the decisions used to determine the reportability of the event.
- Documentation of the final assessment of the event and any corrective or remedial action taken. If no corrective action is taken, a justification shall be provided.
- Copies of reports and other information submitted to the applicable authorities.
- Copies of information submitted to distributors or customers.
- Copies of any other information required regulations.
- Copy of the device history record, if applicable.

7.2. FDA requests: If FDA verbally requests additional information, GT Medical' Quality Representative or delegate shall ask to follow up such requests in writing.

7.3. Retention: Retention times for reporting and recall files must be in accordance with Document and Record Controls procedure as per SOP-001, Quality Manual.

8. MINIMUM NECESSARY REQUIREMENTS FOR PROTECTED HEALTH INFORMATION (PHI)

8.1. It is possible that PHI may be disclosed to GT Medical in a complaint or adverse event report, as covered providers (per 45 CFR 160.163) may disclose PHI to medical device manufacturers subject to FDA jurisdiction for purposes related to regulatory, safety, and effectiveness of FDA-regulated product. In this case, GT Medical may be required to maintain PHI to comply with quality record requirements.

8.2. GT Medical devices do not store, transmit, receive, and/or maintain PHI, and within the scope of this quality management system process, GT Medical does not provide services to/for any health care provider, and/or act on behalf of any health care provider. Therefore, GT Medical is not a *covered entity* or *business associate* per 45 CFR 160.163 and has only developed provisions to comply with the Minimum Necessary Standard (Reference 45 CFR 164.502(b), 164.514(d)), as follows:

8.2.1. GT Medical uses and/or disclosures of PHI shall only include communication or reporting to regulatory agencies, such as the FDA, as required or as requested by the agency and contract manufacturers who may need to participate in product investigations.

8.2.2. GT Medical shall not make requests for PHI for the complaint handling, reporting, and recall process unless the information is necessary to perform a thorough product investigation.

8.2.3. GT Medical has taken steps to limit access to quality records which may contain PHI, by defining responsibilities within the current SOP and storing them in accordance with SOP-005 Electronic Tools Procedure.

8.2.4. If GT Medical determines a need for the use, disclosure, or request for other business processes, appropriate provisions shall be established to ensure compliance to the applicable regulation.

9. APPENDICES

9.1. Appendix A: Customer Complaint Flowchart

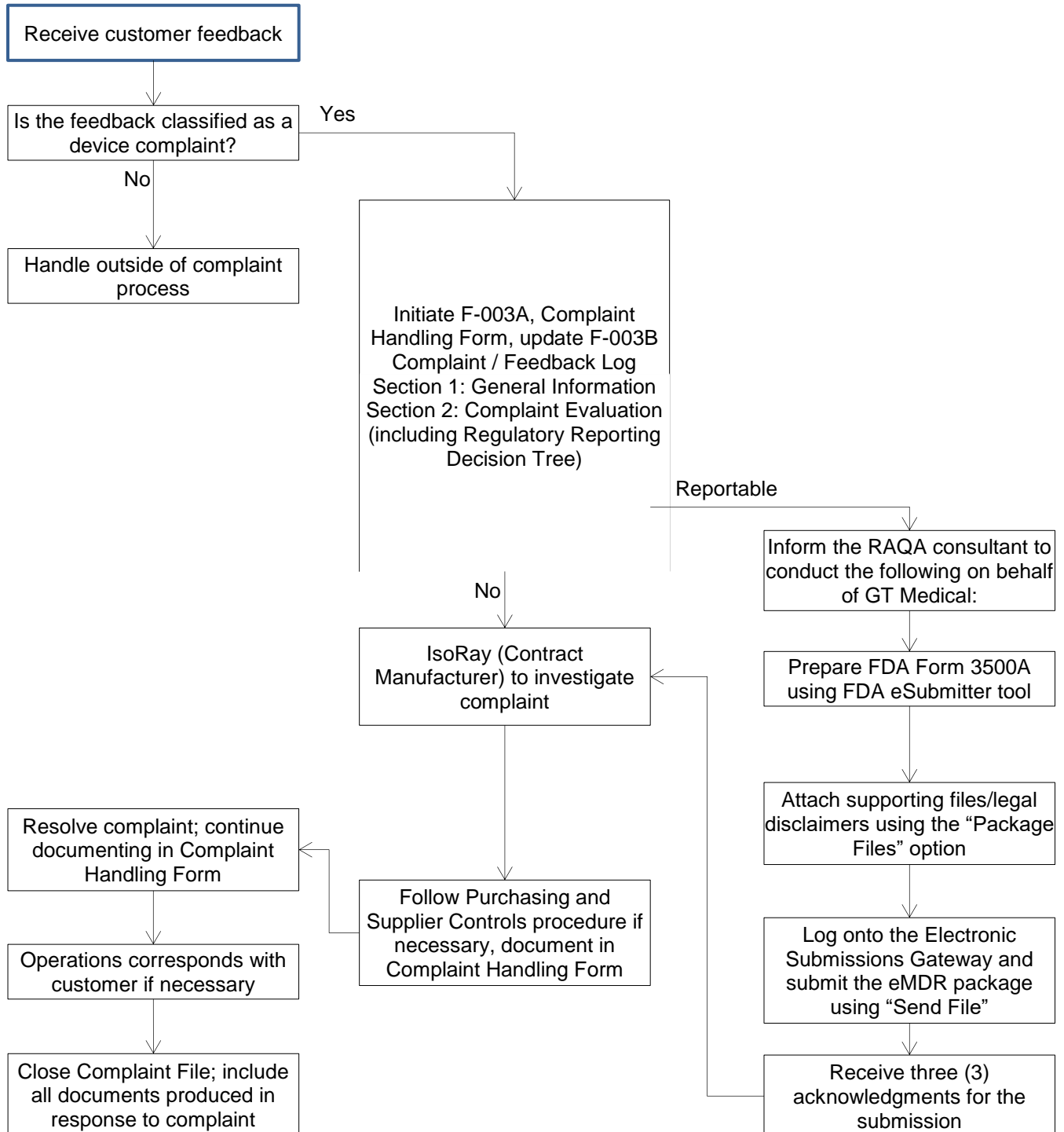
9.2. Appendix B: Reportable Event Timeline Table

10. DOCUMENT HISTORY

Functional Area	Signature & Date
Operations	<p>Hernan Lopez <i>Hernan Lopez</i> 30 Nov 2018 05:22:052-0800 REASON: I am approving this document. 72eef047-7bbe-4092-82b1-f04e00c2e31e</p>
Quality	<p>Michelle Lott <i>Michelle Lott</i> 26 Nov 2018 11:41:042-0800 REASON: I am approving this document. f7e7590f-6690-4b5c-92a2-9498dd850663</p>
Regulatory	<p>Jessica Newhard <i>Jessica Newhard</i> 03 Dec 2018 06:49:041-0800 REASON: I am approving this document. 3bd17091-2c34-4925-88ed-391ad6b1da50</p>

REVISION HISTORY		
Rev. #	Released Date (YYYY-MM-DD)	Author
1	2018-05-14	Michelle Lott
2	2018-09-05	Raines DeMint
3	2018-10-10	Anne Brazeal
4	2018-11-26	Raines DeMint

APPENDIX A – Customer Complaint Flowchart



APPENDIX B – Reportable Event Timeline Table

Type of Reportable Event	FDA Action
Requires remedial action to prevent an unreasonable risk to the public	5 working days of becoming aware
Death or Serious Injury as a result of the device	30 calendars days
Remedial action is required to prevent death or serious injury	5 Work Days
Report requested by the FDA	5 Work Days
No injury or death occurred, but could cause injury or death upon recurrence	30 Days
Additional information is acquired since initial report	Supplemental Report


MySignatureBook V3.12


Validation Report as of: 04 Dec 2018 13:37:043-0800


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Subject CN MSB
Subject DN EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email operations@msbdocs.com
Serial # 277155780700783329438831339513496021584
Issuer DN CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time 03 Dec 2018 06:49:041-0800

 The Certificate chain was successfully built to a Trusted Root Certificate.

 The Signer's identity is valid.

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Audit Trail Report

Date	User	Document	Action	Details
26 Nov 2018 11:22:022-0800	Maria Laitenberger		Started	The custodian composed the ePak successfully. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
26 Nov 2018 11:22:055-0800	Michelle Lott		RequestSent	Sign request sent to ePak recipient. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663
26 Nov 2018 11:22:055-0800	Maria Laitenberger		RequestSent	Sign request sent to ePak recipient. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
26 Nov 2018 11:22:055-0800	Raines DeMint		RequestSent	Sign request sent to ePak recipient. User UUID : 2ee4a9ef-4d1a-4598-bb7f-8eeac6189470
26 Nov 2018 11:22:055-0800	Matt Likens		RequestSent	Sign request sent to ePak recipient. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4
26 Nov 2018 11:22:055-0800	Hernan Lopez		RequestSent	Sign request sent to ePak recipient. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e
26 Nov 2018 11:22:055-0800	John Baker		RequestSent	Sign request sent to ePak recipient. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5
26 Nov 2018 11:22:055-0800	David Brachman		RequestSent	Sign request sent to ePak recipient. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2
26 Nov 2018 11:22:055-0800	Craig Bushnell		RequestSent	Sign request sent to ePak recipient. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34
26 Nov 2018 11:22:055-0800	Jessica Newhard		RequestSent	Sign request sent to ePak recipient. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50
26 Nov 2018 11:22:055-0800	Austin Feldman		RequestSent	Sign request sent to ePak recipient. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe
26 Nov 2018 11:24:045-0800	Maria Laitenberger	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have reviewed this document. User UUID : fff18bac-7002-4b20-9ce3-567169aab764 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
26 Nov 2018 11:25:002-0800	Maria Laitenberger	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : fff18bac-7002-4b20-9ce3-567169aab764 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054
26 Nov 2018 11:39:053-0800	Michelle Lott	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
26 Nov 2018 11:40:052-0800	Michelle Lott	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
26 Nov 2018 11:41:024-0800	Michelle Lott	SOP-002 Purchasing and Supplier Controls Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 2215ca50-eb11-4abe-a50a-34fe27715153
26 Nov 2018 11:41:043-0800	Michelle Lott	SOP-003 Complaint Handling, Reporting, and Recall Rev4.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 8a13de9f-3f26-4e97-899a-51bb7d5ad693
26 Nov 2018 11:42:002-0800	Michelle Lott	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 40b9fbb3-45bd-4dd4-b84b-f339cbe81db
26 Nov 2018 11:42:028-0800	Michelle Lott	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
26 Nov 2018 11:43:000-0800	Michelle Lott	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
26 Nov 2018 11:43:030-0800	Michelle Lott	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054
27 Nov 2018 11:39:053-0800	Maria Laitenberger		StarredByDelegation	EPak starred by a delegation. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
27 Nov 2018 11:39:053-0800	Maria Laitenberger		Delegated	Maria Laitenberger<marial@leanraqasystems.com> delegated the ePak to another signer Raines Demint<rainesd@leanraqa.com> Previous Signer: Raines DeMint<rainesd@leanraqasystems.com> Message: User UUID : fff18bac-7002-4b20-9ce3-567169aab764
27 Nov 2018 11:41:017-0800	Raines Demint	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 7321d07e-0a33-4508-bc91-bbfbbd41c5c6 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054

28 Nov 2018 14:45:051-0800	Matt Likens	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
28 Nov 2018 18:24:027-0800	Craig Bushnell	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
28 Nov 2018 18:25:023-0800	Craig Bushnell	TSS-001_2018-11-26_CBushnell.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34 Document UUID : 1fcb0910-90f4-415c-a752-b6987530c164
29 Nov 2018 10:36:014-0800	Austin Feldman		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe
29 Nov 2018 10:36:017-0800	Jessica Newhard		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50
29 Nov 2018 10:36:020-0800	David Brachman		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2
29 Nov 2018 10:36:023-0800	John Baker		StarredByReminder	EPak starred by a reminder to the signer. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5
29 Nov 2018 10:36:025-0800	Hernan Lopez		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e
29 Nov 2018 10:46:015-0800	Matt Likens	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
30 Nov 2018 05:21:052-0800	Hernan Lopez	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
30 Nov 2018 05:22:013-0800	Hernan Lopez	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
30 Nov 2018 05:22:031-0800	Hernan Lopez	SOP-002 Purchasing and Supplier Controls Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 2215ca50-eb11-4abe-a50a-34fe27715153
30 Nov 2018 05:22:053-0800	Hernan Lopez	SOP-003 Complaint Handling, Reporting, and Recall Rev4.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 8a13de9f-3f26-4e97-899a-51bb7d5ad693
30 Nov 2018 05:23:011-0800	Hernan Lopez	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 40b9fbb3-45bd-4dd4-b84b-f390cbe81db
30 Nov 2018 05:23:033-0800	Hernan Lopez	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
30 Nov 2018 05:24:005-0800	Hernan Lopez	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
30 Nov 2018 05:24:028-0800	Hernan Lopez	TSS-001_2018-11-26_HLopez.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : cdbca299-3d3a-4aef-b7d4-6564c23fb711
02 Dec 2018 07:45:010-0800	Austin Feldman	TSS-001_2018-11-26_AFeldman.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe Document UUID : 698858a6-fc6a-4d39-954d-01ab205d63c4
02 Dec 2018 10:25:017-0800	David Brachman	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
02 Dec 2018 10:26:014-0800	David Brachman	TSS-001_2018-11-26_DBrachman.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2 Document UUID : ded7a4d6-e150-4610-8327-329844249aea

03 Dec 2018 06:48:040-0800	Jessica Newhard	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
03 Dec 2018 06:49:003-0800	Jessica Newhard	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
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03 Dec 2018 06:51:019-0800	Jessica Newhard	TSS-001_2018-11-26_JNewhard.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 9732b790-2038-4f44-80b8-fcfc2f949bc
03 Dec 2018 19:43:053-0800	John Baker	TSS-001_2018-11-26_JBaker.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5 Document UUID : 5278beff-309d-4378-8cae-cf40ad9de034
04 Dec 2018 13:20:059-0800	Matt Likens	TSS-001_2018-11-26_MLikens.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 6e427ba3-e577-42c7-9352-5d9b984a124c
04 Dec 2018 13:20:059-0800	Maria Laitenberger		Completed	The ePak completed the workflow successfully custodian. User UUID : fff18bac-7002-4b20-9ce3-567169aab764