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1.0 Introduction

The purpose of this document is to define product design inputs of the *Lumevia*.

This document was created during the planning phase of the project in accordance with ISO 13485:2016 and shall describe the design inputs relating to (a)…

2.0 Product Description

The Lumevia shall consist of a package containing a handle and an insertion tube for placement within the uterine cavity; a flexible polymer coated T-shaped frame; two integrated drug delivery channels for levonorgestrel and ibuprofen; and a removal thread.

The device is intended to be used by a licensed health professional, specializing in women's health, for patients seeking long-term contraception. Requirements for Lumevia IUD candidates remain consistent with current clinical guidelines until further data becomes available. The device shall be designed to ensure controlled hormone release for pregnancy prevention, while providing effective pain relief for overall experience.

Briefly, a hormonal IUD is often described as a long-acting contraceptive device that releases hormone locally to prevent pregnancy. The process starts with the release of levonorgestrel, which thickens the cervical mucus (Lanzola & Ketvertis, 2023). This creates a barrier that inhibits the motility of sperm to travel through the cervix and into the uterus and thus reducing chances of fertilization (Forsythe & Shefras, 2024). Levonorgestrel can also cause the uterine lining (endometrium) to become thinner, making it difficult for a fertilized egg to implant (Forsythe & Shefras, 2024). In some

cases, the hormonal IUD can suppress ovulation, meaning that it stops the release of an egg, and overall reduce the likelihood of pregnancy (Forsythe & Shefras, 2024).

The proposed device is intended to provide a controlled hormone and anti-inflammatory release agents, ensuring effective contraception and pain-relief under natural conditions. This device is designed to ensure optimal contraception without disruption the equilibrium of the reproductive system and maintain proper hormone regulation and uterine function.

2.1 Device Components

The device is broken down into the following components. Appendix 1 shows these components and the corresponding measurements variables.

1) Handle
    a. Slider
2) Insertion Tube
    a. Flange
3) IUD
    a. T-shaped frame
    b. Hormone cylinder
    c. Pain medication cylinder
    d. Removal thread

3.0 Required Standards

The following documents were used as sources.

ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14937:2009	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of sterilization process for medical devices
ISO 11607-1:2019/Amd1:2023	Packing for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information supplied – Part 1: General requirements
ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 10993-10:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

The following documents were used to guide the development of this *Product Design Inputs Specification Document*.

QF731.01	Market Requirements Specifications
QF735.01	Risk Management Plan

4.0 Product Design Inputs

Please refer to following documentation concurrently for ease of readability of this section:

- ***QF371.01*** *Version 2.0 – Marketing Requirements Specification*

- ***QF735.01*** *Version 2.0 – Risk Management Hazard Analysis*

Missing MRS

4.1.6 The system shall be replaced or removed after a period of eight years

4.1.7 The system shall only be used in eligible patients between 18 to 65 years of age.

The total system price shall be no greater than 10% of the price of the Mirena IUD.

All of section 4.2

4.3.2 A history and physical examination of the patient shall be performed before use.

4.3.5 to 4.3.13

4.5.1 The patient shall have a follow-up with a physician after device insertion.

Not sure where to fit – MRS

4.1.8 The system shall include a disposable inserter

4.1.9 The system shall include a handle to hold the disposable insert.

4.3.3 An open or unsterilized system component shall be discarded.

4.4.6 The device shall have a shelf life of 36 months.

4.5.2 The device shall be sold with all required components to complete the insertion procedure.

Missing risks

U5: Premature removal by the patient

B2: Ectopic pregnancy

C1: Particles on the device

IM2: Allergen on surface of device

I1: Faint labels on packaging

MN1: Device malfunction: Worker misses a component of the device such as pain medication

MN4: Device malfunction: Worker does not perform a quality check of a component

MN5: Device malfunction: Old design files are sent to manufacturer

MN6: Device malfunction: Not following engineering design file

MN7: Device malfunction: Engineering design is not specific enough

Connected to a design input but unsure:

S2: Failure to load ibuprofen correctly

D2: Fragmentation upon removal

IM1: Allergen is a part of the device

MN2: Labeling is missing

4.1 IUD Frame Requirements (IRS)

In this section, the design inputs for the IUD frame are discussed. This is the part of the device that sits in the uterus for the duration of the device use.

ID #	MRS #	HA #	Design Inputs
Mechanical + Physical Material Properties			
IRS 1	4.4.2	U1, U4	The IUD frame shall be T-shaped.
IRS 2		U4, B3	The T-shape of the IUD frame shall have rounded edges.
IRS 3	4.4.2		The IUD frame shall be no larger than 32mm and no longer than 36mm.
IRS 4			The T-frame of the IUD shall be symmetrical about the center.
IRS 5			The IUD frame's cylindrical reservoir shall be 25mm long.
IRS 6			The IUD frame shall contain a white or almost white cylindrical reservoir.
IRS 7	4.3.4	D1	The end of the cylindrical reservoir contains a circular loop.
Biocompatibility			
IRS 8	4.4.1	U1,U4, D2, B3, B4, IM1	The T-frame of the IUD shall be made of polyethylene.
IRS 9		B4	The IUD frame's cylindrical reservoir shall be made of polydimethylsiloxane – a mixture of levonorgestrel and silicone.
Functionality			
IRS 10		U3	The IUD frame's cylindrical reservoir shall contain 2 distribution channels, stacked on top of each other.
IRS 11	4.1.5 4.4.3		One of the distribution channels of the IUD frame's cylindrical reservoir shall contain 52mg of levonorgestrel.
IRS 12	4.1.1 4.1.3		The IUD shall release levonorgestrel at a rate of 20ug/24 hours into the uterine cavity.

	4.1.5		
IRS 13	4.1.2 4.4.4	U3, S2	One of the distribution channels of the IUD frame's cylindrical reservoir shall contain 2.5 mg of ibuprofen.
IRS 14	4.1.2 4.1.3	U3, S2	The IUD shall release ibuprofen at a rate of 200-500ug/day into the uterine cavity over a period of 5 days.
IRS 15	4.1.2 4.4.4	U3, S2	The ibuprofen distribution channel shall be 7mm long and located in the first half.
IRS 16	4.1.5 4.4.3		The levonorgestrel distribution channel shall be 22mm long and located in the second half.
IRS 17	4.1.3 4.1.4		The IUD frame shall be inserted within a 6-10cm depth into the uterus.

4.2 Insertion Tube Requirements (TRS)

In this section, the design inputs for the insertion tube of IUD are described. This is the part of the system that is used to insert the IUD frame into the uterus.

ID #	MRS #	HA #	Design Inputs
Mechanical + Physical Material Properties			
TRS 1			The insertion tube shall have an outer diameter of 4.4mm.
TRS 2			The insertion tube shall have a two-sided symmetric body.
TRS 3		U2	The insertion tube shall be pre-bent.
TRS 4			The insertion tube shall be 200mm long.
TRS 5			The insertion tube shall be translucent.
TRS 6		S3	The insertion tube shall have markings for each cm from 1 to 10cm from its end where the IUD frame is positioned.
TRS 7		U2	The insertion tube shall have an opening to hold the IUD frame into place.

TRS 8		U2	The insertion tube shall include knobs to lock the IUD frame into place once positioned.
TRS 9			There shall be a flange located at the 65mm mark from the top of the insertion tube.
TRS 10			The flange shall have a top section, 5mm thick and 5.4mm in outer diameter with a bottom section, 5mm thick and 5mm in outer diameter.
TRS 11			The flange shall be teal.

4.3 Handle Requirements (HRS)

In this section, the design inputs for the handle used to manipulate the insertion tube are described. The insertion tube and handle together compose the inserter system used for IUD device installation.

ID #	MRS #	HA #	Design Inputs
Mechanical + Physical Material Properties			
HRS 1			The handle shall have a two-sided symmetric body.
HRS 2			The handle shall have an ergonomic shape to operate with one hand.
HRS 3			The handle shall have no sharp edges.
HRS 4			The handle shall be 150mm in length, 30mm in width at the top, 40mm in width at the bottom and 25mm width in the center.
HRS 5			The handle shall have a rectangular cutout with one rounded end on its top part.
HRS 6	4.1.10		There shall be a slider at the center of the top half of the handle.
HRS 7			The slider shall have an ergonomic shape to be pushed up or down with one finger.
HRS 8			The slider shall be positioned onto the insertion tube.

HRS 9		S3	There shall be two ovals drawn on the handle to mark the slider's initial position.
HRS 10			There shall be an arrow pointing upwards on the slider.
HRS 11			The slider shall be teal.
HRS 12	4.3.4 4.4.5	D1, D3	The handle contains two removal threads that connect onto the cylindrical loop at the end of the IUD frame.
HRS 13			The handle shall be white.
Functionality			
HRS 14			There shall be a mechanism pushing the IUD inwards into the insertion tube when the slider is pushed up from the initial position.
HRS 15			There shall be a mechanism pushing the IUD outwards into the uterine cavity from the insertion tube when the slider is pushed down to the initial position mark.
HRS 16			Holding the slider all the way shall permit smooth removal of the insertion tube from the uterus.
Biocompatibility			
HRS 17	4.3.4 4.4.5	D1, D3, B4, IM1	The removal threads of the IUD frame are made of monofilament brown polyethylene.

4.4 Packaging and Labelling Requirements (PRS)

ID #	MRS #	HA #	Design Inputs
PRS 1		S1	The complete Mirena system shall be packaged in a thermoformed blister package with a peelable lid.
PRS 2		S1, B1	The Mirena system shall be sterilized prior to packaging.
PRS 3	4.3.1	S1, B1	The thermoformed blister package shall be sterile.
PRS 4		S3, MN2	The package shall have a sticker containing product information.

PRS 5	4.1.11	S3, MN2, MN3	The product information sticker shall indicate contents, product disclaimer, dosage, storage, manufacturing information and lot number and expiry date.
PRS 6			The package shall be contained in a rectangular carton 300mm x 50mm x 40mm.
PRS 7		S3, MN2	The device carton shall contain a patient information booklet and physician labelling.
PRS 8		D4, MN2	The device carton shall indicate device disposal instructions.
PRS 9	4.1.11	S3, MN2, MN3	The device carton shall indicate serial number, lot number and expiry date.
PRS 10		S3, MN2	The device carton shall indicate the name of the product and drug quantity.
PRS 11		S3, MN2	The device carton shall indicate who the product is manufactured for.
PRS 12		S3, MN2	The device carton shall indicate where the product was manufactured.
PRS 13		S3	The device carton shall indicate manufacturing month and year.

5.0 Manufactured for

Lumevia Health

170 College St., Room 322, Toronto, ON, M5S 3E3

6.0 Indications for use

The device is intended to be used by healthcare professionals trained and qualified for administrating a hormonal intrauterine device (IUDs). It is specifically indicated

for patients seeking long-term contraception and a pain-free insertion experience. It is meant to be implanted in the uterus, specifically within the uterine cavity. By delivering both, levonorgestrel and ibuprofen, this device provides an added benefit of reducing cramping and inflammation during an IUD procedure. This device is intended to enhance patient comfort, improve the overall experience, and support long-term contraceptive use. Patients must be of 18 years of age and menstruation must be present for the reproductive cycle to occur.

Associated Hazard Analysis:

7.0 Directions for use

This is an overview of the IUD procedure. More details are found in the IUD procedure protocol

i. The device will be transported from its storage space to the exam room and kept in the sterile field until it is ready to be inserted
ii. The trained healthcare professional will perform a bimanual exam to assess the size, shape and position of the participant's uterus
iii. The device will be unpackage by the trained healthcare professional in a sterile manner
iv. The IUD will be loaded in the insertion tube by pushing the slider forward as far as possible in the direct of the arrow and holding the position
v. The upper edge of the flange will be set to correspond with the participant's uterine depth (in centimeters)

vi. While maintaining forward pressure on the slider, the inserter will be inserted in the cervix until the flange is about 1.5-2 centimetres from the cervix

vii. The slider will be pushed downwards until the designated mark on to release the IUD arms, allowing 10 seconds for full deployment

viii. The inserter will be gently advanced towards the fundus of the uterus, until the flange touches the cervix

ix. The inserter will be released from the IUD and pulled out of the uterus by moving the slider all the way down

x. The removal thread will be cut perpendicularly, leaving about 3 centimetres of length within the cervix

xi. Post-procedure care instructions will be provided, including expected side effects and follow-up recommendations.

Associated Hazard Analysis:

8.0 Storage and Transportation

The Lumevia shall be stored at 25C. For transportation, the device shall be transported within USP Controlled Room temperature ranges, i.e. between 15 to 30C. The Lumeva shall be used within 36 months of manufacture and discarded upon expiry.

9.0 Adverse Effects

10.0 Contraindications

Do not use this device with patients that have an allergy to any of the materials used in the manufacturing of the device or to the drugs administered through the device. Do not use this device on patients who:

- are pregnant or suspecting pregnancy
- are dealing with any pelvic, uterine or vaginal infections
- are dealing with a liver disease or tumour
- have an immunodeficiency disorder
- have any type of cancer
- have a previously inserted IUD that has not been removed

Consult a qualified health practitioner before adopting the Lumevia, for patients who:

- are under 18 years of age or over 65
- are breastfeeding
- have given birth in the last 36 weeks
- have a history of irregularity or issues with menstruation
- have or have family history related to heart or liver issues and/or diabetes
- have or have family history related blood pressure
- are taking any other medication
- wear contact lenses
- smoke

- have a BMI outside the normal range
- have a history of mental health conditions

11.0 References

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12.0 Review and Approval

Approval	Position	Date
	Name: **Title: Chief Executive Officer**	
	Name: **Title: Chief Technology Officer**	
	Name: **Title: Chief Research Officer**	

13.0 Document History

Revision	Effective Date	Author	Change Request #	Change Summary
1.0	April 1, 2025		N/A	Initial Release