May 19, 2022

LISA Laser Products GmbH
Ralf Balkenhol
Quality Manager
Albert-Einstein-Str, 4
Katlenburg-Lindau Niedersachsen 37191
Germany

Re: K211534
Trade/Device Name: RevoLix HTL
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2022
Received: April 18, 2022

Dear Ralf Balkenhol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211534

Device Name
RevoLix HTL

Indications for Use *(Describe)*

Soft tissue treatments and lithotripsy in the field of urology: In CW mode the indications for use are:

Enucleation of the prostate

Vaporization of the prostate

Opening of ureter and urethral strictures

Bladder neck incisions

Bladder tumor resections

Ureter and kidney tumor ablation

Condyloma and penile tumor excision

In PULSED mode the indications for use are: Lithotripsy of bladder, ureter and kidney stones including fragmentation and dusting

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k)_Summary

General Provisions

510(k) Owners Name:	LISA Laser Products GmbH Albert-Einstein-Str. 4 37191 Katlenburg-Lindau, Germany
Contact Person:	Dr. Ralf Balkenhol Quality Manager
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Classification:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulation:	21 CFR § 878.4810
Regulatory Class:	II
Proprietary Name:	RevoLix HTL
Common Name:	Powered Laser Surgical Instrument
Date Summary Prepared:	April 30, 2021

Name of Predicate Device(s)

- Sphinx jr. Holmium Laser (Primary Predicate Device) - **K132975**
- RevoLix 200 (Secondary Predicate Device) - **K110941**
- Lumenis Pulse 120H (Reference Device) - **K140388**
- Quanta 150W laser, (Reference for pulse mode comparison) - (K201455)

Intended Use

The RevoLix HTL is a surgical laser intended for non-invasive, invasive, and surgically invasive incision, excision, resection, removal, vaporization and coagulation of soft tissue in urology, and for the invasive and surgically invasive destruction of stones in the urogenital tract (bladder, ureter, kidney).

Indications for Use

The indications for use of the RevoLix HTL are Soft Tissue treatments and Lithotripsy in the field of urology: In CW mode the indication for use are: Enucleation of the prostate, Vaporization of the prostate, Opening of ureter and urethral strictures, Bladder neck incisions, Bladder tumor resections, Ureter and kidney tumor ablation, Condyloma and penile tumour excision; in PULSED mode the indications for use are: Lithotripsy of bladder, ureter and kidney stones including fragmentation and dusting.

Device Description

The RevoLix HTL is a surgical diode-pumped solid-state laser (DPSS). The laser radiation is generated by the excitation of a solid-state Tm-YAG laser crystal using a QCW laser diode. The laser radiation is cw (continuous wave) or delivered in pulses. The emitted laser radiation has a wavelength of 2,013 nm, which is invisible infrared. RevoLix HTL is a floor standing mobile device. The device is operated by using an operating console equipped with a touch screen and control elements. The laser emission is triggered by a foot switch. The RevoLix HTL operating console enables the user selecting the desired treatment parameters such as laser power and laser energy delivery modes: continuous or pulsed. The GUI is also used to display to the user all operational settings and operational states. The laser is activated by a foot switch**.**

The system design and software ensure that the energy output is delivered as intended by the user. The laser radiation is focused by a fiber coupler into a flexible silica laser fiber which delivers the laser radiation to the surgical site.

Technological Characteristics

Substantial Equivalence - Table

Substantial equivalence of RevoLix HTL (Subject Device) is based on the same intended use and similarities in technological characteristics and operation principle with the Sphinx jr. Holmium Laser (Primary Predicate Device) (**K132975**) and RevoLix 200 (Secondary Predicate Device**) (K110941)** and which are legally marketed Class II medical devices under 21 CFR 878.4810, i.e., laser surgical instrument for use in general and plastic surgery and in dermatology.

For aspects concerning the higher pulse repetition rate of the RevoLix HTL compared to the predicate devices, the Lumenis Pulse 120H **(K140388)**, and Quanta 150W laser (**K201455),** for pulse mode comparison which is legally marketed Class II medical devices under 21 CFR 878.4810, i.e., laser surgical instrument for use in general and plastic surgery and in dermatology, is used as a reference device to provide evidence for safety and effectiveness.

NOTE: *"Pages 8-9 show an updated table of the comparison of all technical parameters split to tissue and lithotripsy mode. An additional reference device (Quanta Cyber Ho 150W K201455) has been added to the table.*"

Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
Manufacturer	LISA Laser Products GmbH	LISA Laser Products GmbH	LISA Laser Products GmbH	Lumenis Ltd.	--
Product Code	GEX	GEX	GEX	GEX	Yes, same product code
Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Yes, same regulation
Device Class	II	II	II	II	Yes, same device class
Intended Use	The RevoLix HTL is a surgical laser intended for non-invasive, invasive, and surgically invasive incision, excision, resection, removal, vaporization and coagulation of soft tissue in urology, and for the invasive and surgically invasive destruction of stones in the urogenital tract (bladder, ureter, kidney).	The Sphinx jr. laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft and hard tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gasteroenterology, Arthroscopy, Discectomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery	The RevoLix 200 laser systems and their fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery. and Arthroscopy	Lumenis Pulse 120H is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; ENT. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.	Yes, same intended use with the primary predicate device. Large degree of overlap with the secondary predicate
Indications for use	Soft tissue treatments and lithotripsy in the field of urology: • Enucleation of the prostate • Vaporization of the prostate • Opening of ureter and	- Urology Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:	- Urology Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:	- Urology Endoscopic transurethral incision of the prostate (TUWP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser	Yes, equivalent The RevoLix HTL has the same indications in urology. Predicate devices have additional indication in other fields

Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
	urethral strictures • Bladder neck incisions • Bladder tumor resections • Ureter and kidney tumor ablation • Condyloma and penile tumor excision • Lithotripsy of bladder, ureter and kidney stones including fragmentation and dusting	Urethral Strictures Bladder Neck Incisions Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors. Ablation of Benign Prostatic Hypertrophy (BHP) Resection of the Prostrate Condylomas Lesions of external genitalia Lithotripsy and Percutaneous Urinary Lithotripsy Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi Endoscopic fragmentation of kidney calculi Treatment of steinstrasse when guide wire cannot be passed Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology and Plastic surgery, General Surgery, Arthroscopy.	Urethral Strictures Bladder Neck Incisions (BNI) Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors. Ablation of Benign Prostatic Hypertrophy (BHP), Transurethral incision of the prostate (TUIP) Laser Resection of the Prostrate (HoLRP) Laser Enucleation of the Prostate (HoLEP) Laser Ablation of the Prostate (HoLAP) Condylomas Lesions of external genitalia Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology and Plastic surgery, General Surgery, Arthroscopy	enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH) - Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of. • bladder; • superficial and invasive bladder, urethral and ureteral tumors; • condylomas; • lesions of external genitalia; • ureteral and penile haemangioma; • ureteral strictures; • bladder neck obstructions - Urinary Lithotripsy including: endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi,	

Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
				including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones; treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed. Arthroscopy, General Surgery, ENT Surgery, Gynecological Surgery, Gastroenterology Surgery, Pulmonary Surgery, Dermatology and Plastic Surgery	
Laser type	Tm:YAG Diode Pumped Solid State laser	--	Tm:YAG Diode Pumped Solid State laser		Yes, same laser type
	--	HoYAG flash lamp pumped solid state laser	--	HoYAG flash lamp pumped solid state laser	--
Wavelength	Tm:YAG 2013 nm (±10 nm)	--	2.01 µm		Yes, same wavelength
	--	2123 nm (± 3 nm)	--	2.1 µm	Equivalent, the difference in wavelengths has been shown in V&V tests to have negligible effect on safety and performance.
CW mode	Power: 5 – 150W RevoLix HTL eco: 5 - 75 W	--	Power: max 200W	—	Equivalent, higher power in CW mode. Same / lower power compared to reference device
Pulse mode	Average power: 5 - 150W	Average power: max. 30W	Average Power: max. 200W	Average Power: max 120W	Equivalent, the average power in Pulsed mode for

Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
	RevoLix HTL eco: 5 - 75 W				RevoLix HTL exceeds that of the Sphinx jr. This represents a technical advancement and is unlikely to affect safety and performance of the RevoLix HTL.
	Pulse peak power: max. 1.3 kW	Pulse peak power: max. 18 kW	Pulse peak power: max. 200W	unknown	The RevoLix HTL has a lower pulse peak power.
	Pulse energy: 0.3 - 4.5 J	Pulse energy: 0.3 - 3.5 J	n/a	0.2 – 6 J	The RevoLix HTL is capable of achieving a pulse energy in the same range as in the equivalent devices.
	Pulse repetition rate: 5 - 300 Hz	Pulse repetition rate: 1 - 20 Hz	Pulse repetition rate: 0.5 - 10 Hz	Pulse repetition rate: 5 - 80 Hz	The RevoLix HTL is capable of achieving a pulse repetition rate in the same range as in the equivalent devices.
	Pulse duration: 200 - 4750 µs	Pulse duration: max. 650 µs	Pulse duration: 50 - 1000 ms	Pulse duration: short / mid / long max 1300 µs	The RevoLix HTL is capable of achieving a pulse duration in the same range as in the equivalent devices.
Aiming beam	Wavelength: 532 nm (green)	Wavelength: 635 nm (red) or 532 nm (green)	Wavelength: 635 nm (red)	Wavelength: 532 nm (green)	Yes, equivalent. RevoLix HTL only offers a 532 nm beam, the other devices also offer a 635 nm beam. The wavelength of the aiming beam has negligible effect on safety and performance.
	Power: 1 - 3 mW	Power: max. 5 mW	Power: max. 1 mW,	Power: max. 5 mW,	Yes, similar. The power of the aiming beam offered by RevoLix HTL lies

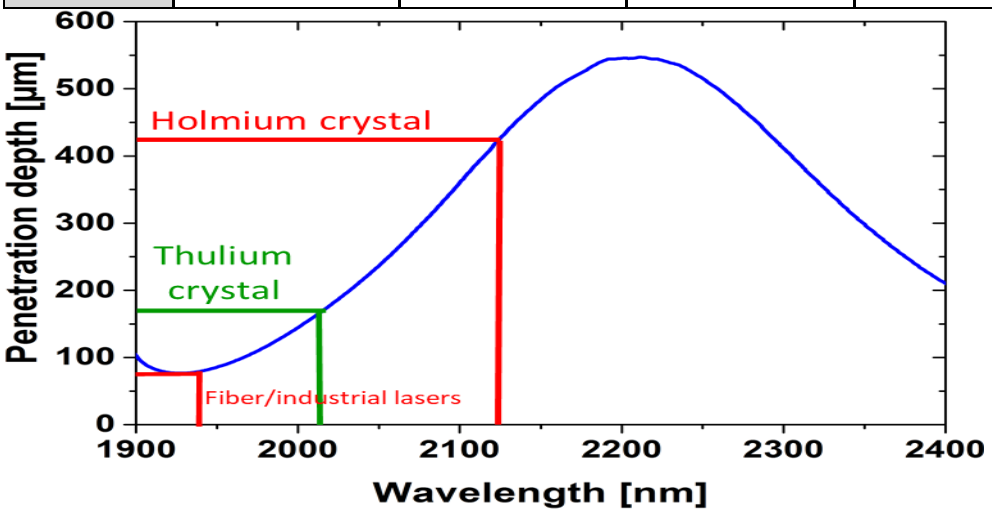
Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
					in the same range as that of the equivalent devices.
Laser Class	4 (IEC 60825-1) IV (CDRH)	4 (IEC 60825-1)	4 (IEC 60825-1)	4 (IEC 60825-1) IV (CDRH)	Yes, identical
Applied part	Type (IEC 60601-1): BF	Type (IEC 60601-1): BF	Type (IEC 60601-1): BF	Type (IEC 60601-1): BF	Yes, identical
	Beam delivery: silica - silica multimode fibre	Beam delivery: silica – silica multimode fibre	Beam delivery: silica – silica multimode fibre	Beam delivery: silica – silica multimode fibre	Yes, identical
User panel	Colour LCD display (GUI), touch sensitive	Colour LCD Display (GUI), touch sensitive	White/blue LCD display (GUI), 3 buttons, 1 thumbwheel	Colour LCD display (GUI), touch sensitive	Yes, identical with Secondary predicate. Similar to primary predicate
Laser trigger	Foot switch	Foot switch	Foot switch	Foot switch	Yes, identical
Treatment parameters	User selected	User selected	User selected	User selected	Yes, identical
Operating Conditions	Temperature: +15 - +28 °C, Relative humidity: 10 - 90 % (non-condensing), Air pressure: 700 - 1060 hPa	Temperature: +15 - +28 °C, Relative humidity: 10 - 90 % (non-condensing), and Air pressure: 700 - 1060 hPa	Temperature: +18 - +28 °C, Relative humidity: 10 - 90 % (non-condensing), Air pressure: 700 - 1060 hPa	Temperature: +10 – +24 °C Relative humidity: max. 75 %(non-condensing) Air pressure: 77 – 106 kPa	Yes, identical
Shipping& storage Conditions	Temperature: 0 - +70 °C, Relative humidity: 10 - 90 % (non-condensing), Air pressure: 700 - 1060 hPa	Temperature: -5 - +70 °C, Relative humidity: 10 - 90 % (non-condensing), Air pressure: 700 - 1060 hPa	Temperature: +3 - +45 °C, Relative humidity: 10 - 90 % (non-condensing), Air pressure: 700 - 1060 hPa	Temperature: - 20 – 70 °C Relative humidity: 95% at 20 °C non-condensing Air pressure: 77 – 106 kPa	Yes, similar.
Input power	200 V - 240 V, 50/60 Hz, Max. 10 A (1~, N, PE) 110 V - 115 V, 50/60 Hz, Max. 20 A (1~, N, PE)	210 V – 230 V, 50/60 Hz, max. 10 A (1~, N, PE) 110 V – 115 V, 50/60 Hz, max. 20 A (1~, N, PE)	230 V AC, 50/60 Hz, (1~, N, PE), max. 20 A	200 – 240 V AC, 50/60 Hz, max. 46 A	Yes, consistent values for US market
Weight	108 kg	95 kg	approx. 140 kg	240 kg	Yes, similar
Size (HxWxD)	1025 x 450 x 740 mm	1000 x 450 x 740 mm	950 x 420 x 890 mm	105 x 47 x 116 cm	Yes, equivalent sizes. Mobile floor standing devices with castors
Laser safety	FDA CDRH 21 CFR 1040 (Laser Notice 56);	FDA CDRH 21 CFR 1040 (Laser Notice 56)	FDA CDRH 21 CFR 1040 (Laser Notice 56)	FDA CDRH 21 CFR 1040	Yes

Device Name	RevoLix HTL Proposed Device	Sphinx jr. K132975 Primary Predicate Device	RevoLix 200 K110941 Secondary Predicate Device	Lumenis Pulse 120H K140388 Reference Device	Substantial Equivalence?
	IEC 60601-2-22; IEC 60825-1	IEC 60601-2-22; IEC60825-1	IEC 60601-2-22; IEC60825-1	IEC 60601-2-22; IEC60825-1	

TISSUE ContinuousWave (CW) Mode			
Device Name	**RevoLix HTL Proposed Device**	**RevoLix 200 K110941 Secondary Predicate Device**	**Modification**
CW mode	Power: 5 – 150W RevoLix HTL eco: 5 - 75 W	Power: max 200W	Lower output power therefore lower risk
Laser type	Tm:YAG Diode Pumped Solid State laser	Tm:YAG Diode Pumped Solid State laser	No change
Wavelength	2013 nm	2013 nm	No change

LITHOTRIPSY PULSED MODE					
	RevoLix HTL Proposed Device	**Sphinx jr. K132975 Primary Predicate Device**	**Lumenis Pulse 120H K140388 Reference Device**	**Quanta Cyber Ho 150W K201455 Second Reference**	**Modification**
Pulse mode	Average power: 5 - 150W RevoLix HTL eco: 5 - 75 W	Average power: max. 30W	Average Power: max 120W	Average Power: max 150W	Same range of average power
Pulse peak power	max. 1.3 kW	max. 18 kW	>10kW	>10kW	Lower peak power than Holmium based lasers. Thulium higher absorption allows for lower pulse peak powers increasing safety. See graph. Lower pulse peak powers significantly reduce the retropulsion of

					stones which increases the safety. Less chasing of stones around the human anatomy decreasing the risk of misfire laser on tissue
Pulse energy	0.3 - 4.5 J	0.3 - 3.5 J	0.2 – 6 J	5 J	Pulse energy within the range
Pulse repetition rate	5 - 300 Hz	1 - 20 Hz	5 - 80 Hz	up to 100 Hz	Higher dynamic range thanks to the diode pumped technology. The limit has been set to 300 Hz since there is no clinical benefit for > 300 Hz for lithotripsy. There are FDA cleared Thulium Fiber laser with frequency up to 2600 Hz.
Pulse duration	200 - 4750 µs	max. 650 µs	short / mid / long max 1300 µs	up to 1100 µs	Higher dynamic range thanks to the diode pumped technology. Longer pulse is safer will distribute the energy on a longer period.



The blue line of the graph shows the penetration depth of water and aqueous biomedical materials for different laser wavelengths. Holmium lasers emit at 2130 nm and the corresponding penetration depth into tissue/stones is 420 µm. When comparing with Thulium lasers at 2013 nm the penetration is less than 50% (170 µm) lower which enables a higher precision of the ablation process.

Risk Analysis

Risk Analysis was performed to ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices. The Risk Analysis was reviewed by as part of IEC 60601-1 by a recognized testing Laboratory.

Summary of Performance Testing

Performance testing was conducted to verify the performance of the RevoLix HTL and its substantial equivalence with respect to safety and effectiveness to the cleared predicate system.

- Validation and Verification testing confirms that the device performance meets specifications and assures the safety and effectiveness of the System Laser.
- Electrical and laser safety, electromagnetic compatibility testing and other standard tests required to conform to the regulatory standards as follows:
    - IEC 60601-1-2 (Ed. 4.0) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic disturbances - Requirements and tests
    - IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012 (Ed. 3.1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - IEC 62304:2006+A1:2015 Medical devices software - Software life-cycle processes
    - IEC 60601-1-6:2010 + A1:2013 (Ed. 3.1) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - IEC 60601-2-22:2007 + A1:2012 (Ed. 3.1) Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, therapeutic and diagnostic laser equipment
    - IEC 60825-1:2014/AC:2017 Safety of laser products - Part 1: Equipment classification and requirements

Non-Clinical Performance Testing

Software verification and validation testing was conducted, and documentation provided as recommended by FDA Guidance *Content of Premarket Submissions for Software Contained in Medical Devices (2005)* and IEC 62304.

Biocompatibility of the patient contacting materials (laser fibers) was previously submitted in predicate device 510(k)s listed above.

Clinical Performance Data

Clinical data were not deemed necessary as the device is using the same intended use and key technology, operating principles and indications for use as the predicate devices.

Conclusion

The RevoLix HTL device presents the same intended use and similar indications for use as its predicate devices. The RevoLix HTL performs in accordance with its requirements and specifications, in similarity to the predicate devices. The minor design differences do not raise any new safety and/or effectiveness as demonstrated by the performance data. Consequently, the RevoLix HTL was found to perform as well as its predicate and is substantially equivalent to the predicate device.