Sempterber 3, 2024

Quanta System SpA
Bandiera Dario
Regulatory Affairs Manager
Via Acquedotto 109
Samarate, VA 21017
Italy

Re: K242251
Trade/Device Name: Litho 60; Litho 100; Litho 150
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 17, 2024
Received: July 31, 2024

Dear Bandiera Dario:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.09.03 16:21:36 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & Infection Control Devices,
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242251

Device Name
Litho 60;
Litho 100;
Litho 150

Indications for Use *(Describe)*
Litho 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 haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynaecology, ENT and General Surgery.

Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
• Urethral Strictures
• Bladder Neck Incisions (BNI)
• Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors
• Ablation of Benign Prostatic Hypertrophy (BPH)
• Transurethral incision of the prostate (TUIP)
• Holmium Laser Resection of the Prostrate (HoLRP)
• Holmium Laser Enucleation of the Prostate (HoLEP)
• Holmium laser Ablation of the Prostate (HoLAP)
• Condylomas
• Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
• Dehydrate stones
• Endoscopic fragmentation of kidney calculi
• Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology
Open and endoscopic Gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

• Appendectomy
• Polyps
• Biopsy
• Gall Bladder calculi
• Biliary/Bile duct calculi
• Ulcers
• Gastric ulcers
• Duodenal ulcers
• Non Bleeding Ulcers
• Pancreatitas
• Haemorrhoids
• Cholecystectomy
• Benign and Malignant Neoplasm

• Angiodysplasia
• Colorectal cancer
• Telangiectasias
• Telangiectasias of the Osler-Weber-Renu disease
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric Erosions

Arthroscopy
Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:
• Ligament and tendon Release
• Contouring and sculpting of articular surfaces
• Capsulectomy in the Knee
• Chondreplasty in the Knee
• Debridement of inflamed synovial tissue
• Chondromalacia Ablation
• Chondromalacia and tears
• Plica Removal
• Meniscectomy
• Loose Body Debridement
• Lateral retinecular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including
• Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Foraminoplasty
• Percutaneous Cervical Disc Decompression/Discectomy
• Percutaneous Thoracic Disc Decompression/Discectomy

Gynaecology
Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue

ENT
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and cartilage) including:
• Endonasal/sinus Surgery
• Partial turbinectomy
• Polypectomy
• Dacryocystorhinostomy
• Frontal Sinusotomy
• Ethmoidectomy
• Maxillary antrostomy
• Functional endoscopic sinus surgery

General Surgery
Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
• Appendectomy
• Skin incision

• Excision of external and internal lesions
• Complete or partial resection of internal organs, tumors and lesions
• Biopsy

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 K242251

Applicant / manufacturer:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	17th June 2024
Model name:	Litho 60, Litho 100, Litho 150
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Basis for submission:	Device technical modifications
Predicate (original unmodified) device	Litho 60, Litho 100 (K192600) and Litho 150 (K201455) manufactured by Quanta System
Reference device	MultiPulse HoPlus (K161257) manufactured by Asclepion Laser Technologies GmbH

1 Abbreviations

FW= firmware
SW= software

2 Device description

Litho family includes surgical laser devices that are used by health care professionals in professional healthcare environments. Litho family includes the following models: Litho 60, Litho 100 and Litho 150. They differ only for the maximum power: 60, 105 and 152, respectively.
Litho devices are connected to optical fibers accessories (separately FDA cleared: K131473, K160513, K200234).
The device is equipped with a graphical user interface through which the user can set energy, frequency and pulse duration level. Different pre-sets are available among which the so called "special effects": *Virtual Basket* and *Magneto*. *Virtual basket* and *Magneto* are optional configurations.
Virtual basket had been introduced with K192600 (for Litho 60 and Litho 100) and already included in Litho 150 510K (K201455). While, *Magneto* is the object of the present 510K.
Virtual basket consists of two sub-pulses separated by a certain delay. The first pulse generates a cavitation bubble and the second one is emitted when the first bubble reaches its maximum expansion. This allows the stone to be "caught" to be fragmentated. The set energy is the sum of the energy of the two sub-pulses.
While *Magneto* consists of a pulse with a duration higher than standard one (2000 µs vs 1100 µs). Devices with *Magneto* configuration installed are characterized by black covers and Magneto logos.

The device can be divided into four main sections:

- Power electronics: they manage power supplied to all device compartments;
- Control electronics: they mainly consist of a microcontroller board where device main firmware (FW) is resident and a PC embedded with graphical user interface where device software (SW) runs;
- Cooling system: it cools the laser source pumping chamber;
- Optical bench.

3 Comparison with predicate

In Table 1 the main specifications of the subject device are summarized and compared to the predicate/reference devices.

Table 1: Main specifications comparison table.

	Subject device			**Predicate (original unmodified) device**			**Reference device**	**Equivalence rationale**
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
510K	-			K192600	K192600	K201455	K161257	-
Product Code	GEX			The same			The same	-
Laser Sources	CTH:YAG			The same			The same	-
Laser Wavelength (nm)	2100			The same			The same	-
Indications for use	Litho 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 haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynaecology, ENT and General Surgery. <u>Urology</u> Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Urethral Strictures • Bladder Neck Incisions (BNI) • Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors • Ablation of Benign Prostatic Hypertrophy (BPH) • Transurethral incision of the prostate (TUIP) • Holmium Laser Resection of the Prostrate (HoLRP) • Holmium Laser Enucleation of the Prostate (HoLEP) • Holmium laser Ablation of the Prostate (HoLAP) • Condylomas • Lesions of external genitalia			The same			The MULTIPULSE HoPLUS laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynaecology, ENT, Dermatology, Plastic surgery and General Surgery. <u>Urology</u> Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Urethral Strictures • Bladder Neck Incisions (BNI) • Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors	Subject vs reference: Indications of the subject device are a sub-set of the reference. Additional indications of the reference device are highlighted in green.

	Subject device			Predicate (original unmodified) device			Reference device	Equivalence rationale
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
	<u>Lithotripsy and Percutaneous Urinary Lithotripsy</u> • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate • Dehydrate stones • Endoscopic fragmentation of kidney calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed. <u>Gastroenterology</u> Open and endoscopic Gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Appendectomy • Polyps • Biopsy • Gall Bladder calculi • Biliary/Bile duct calculi • Ulcers • Gastric ulcers • Duodenal ulcers • Non Bleeding Ulcers • Pancreatitas • Haemorrhoids • Cholecystectomy • Benign and Malignant Neoplasm • Angiodysplasia • Colorectal cancer • Telangiectasias • Telangiectasias of the Osler-Weber-Renu disease • Vascular Malformation • Gastritis • Esophagitis • Esophageal ulcers • Varices • Colitis						• Ablation of Benign Prostatic Hypertrophy (BPH) • Transurethral incision of the prostate (TUIP) • Holmium Laser Resection of the Prostrate (HoLRP) • Holmium Laser Enucleation of the Prostate (HoLEP) • Holmium laser Ablation of the Prostate (HoLAP) • Condylomas • Lesions of external genitalia <u>Lithotripsy and Percutaneous Urinary Lithotripsy</u> • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate • Dehydrate stones • Endoscopic fragmentation of kidney calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed. <u>Gastroenterology</u> Open and endoscopic Gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Appendectomy • Polyps • Biopsy • Gall Bladder calculi • Biliary/Bile duct calculi • Ulcers	

	Subject device			Predicate (original unmodified) device			Reference device	Equivalence rationale
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
	• Mallory-Weiss tear • Gastric Erosions <u>Arthroscopy</u> Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including: • Ligament and tendon Release • Contouring and sculpting of articular surfaces • Capsulectomy in the Knee • Chondreplasty in the Knee • Debridement of inflamed synovial tissue • Chondromalacia Ablation • Chondromalacia and tears • Plica Removal • Meniscectomy • Loose Body Debridement • Lateral retinecular release Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including • Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Foraminoplasty • Percutaneous Cervical Disc Decompression/Discectomy • Percutaneous Thoracic Disc Decompression/Discectomy <u>Gynaecology</u> Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue <u>ENT</u> Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and cartilage) including: • Endonasal/sinus Surgery • Partial turbinectomy						• Gastric ulcers • Duodenal ulcers • Non Bleeding Ulcers • Pancreatitas • Haemorrhoids • Cholecystectomy • Benign and Malignant Neoplasm • Angiodysplasia • Colorectal cancer • Telangiectasias • Telangiectasias of the Osler-Weber-Renu disease • Vascular Malformation • Gastritis • Esophagitis • Esophageal ulcers • Varices • Colitis • Mallory-Weiss tear • Gastric Erosions <u>Arthroscopy</u> Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including: • Ligament and tendon Release • Contouring and sculpting of articular surfaces • Capsulectomy in the Knee • Chondreplasty in the Knee • Debridement of inflamed synovial tissue • Chondromalacia Ablation • Chondromalacia and tears • Plica Removal • Meniscectomy • Loose Body Debridement	

	Subject device			**Predicate (original unmodified) device**			**Reference device**	**Equivalence rationale**
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
	• Polypectomy • Dacryocystorhinostomy • Frontal Sinusotomy • Ethmoidectomy • Maxillary antrostomy • Functional endoscopic sinus surgery <u>General Surgery</u> Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Appendectomy • Skin incision • Excision of external and internal lesions • Complete or partial resection of internal organs, tumors and lesions • Biopsy						• Lateral retinecular release Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including • Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Foraminoplasty • Percutaneous Cervical Disc Decompression/Discectomy • Percutaneous Thoracic Disc Decompression/Discectomy <u>Pulmonary</u> Open and endoscopic pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and haemsoatis of soft tissue) <u>Gynaecology</u> Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue. <u>ENT</u> Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and cartilage) including: • Endonasal/sinus Surgery • Partial turbinectomy • Polypectomy • Dacryocystorhinostomy • Frontal Sinusotomy • Ethmoidectomy • Maxillary antrostomy	

	Subject device			**Predicate (original unmodified) device**			**Reference device**	**Equivalence rationale**
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
							• Functional endoscopic sinus surgery Dermatology and plastic surgery Incision, excision, resection, ablation, vaporization, coagulation, hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including: • Basal cell carcinomas • Lesions of skin and subcutaneous tissue • Skin tags • Plantar warts • Lesions of skin and subcutaneous tissue • Port wine stains • Papillomas General Surgery Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Appendectomy • Skin incision • Excision of external and internal lesions • Complete or partial resection of internal organs, tumors and lesions • Biopsy	
Pulse width$_{max}$ (µs)	1100	1100	1100	The same			**1700**	Subject vs reference: very similar to the reference device (they differ less than 20%).
Pulse width$_{max}$ (µs) with *Magneto*	-	**2000**	**2000**	-	Not available	Not available		

	Subject device			Predicate (original unmodified) device			Reference device	Equivalence rationale
Model n°	*Litho 60*	*Litho 100*	*Litho 150*	*Litho 60*	*Litho 100*	*Litho 150*	*MultiPulse HoPlus*	-
Repetition rate$_{max}$ (Hz)	60	80	100	The same			The same: 100	-
Energy$_{max}$ (J)	5	5	5	The same			6	The same of unmodified device and lower than the reference device (20% of difference).
Power$_{max}$ (W)	60	105	152	The same			140	The same of unmodified device and very similar to the reference (less than 20% of difference).
With *Virtual basket*								
Energy$_{max}$ (J) per single pulse	2.5	2.5	2.5	The same			Not available	-
Repetition rate$_{max}$ (Hz)	55	70	70	The same			Not available	-
Power$_{max}$ (W)	60	92	92	The same			Not available	-

4 Indication for use

Litho 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 haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynaecology, ENT and General Surgery.

<u>Urology</u>

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors

- Ablation of Benign Prostatic Hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostrate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmium laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
- Dehydrate stones
- Endoscopic fragmentation of kidney calculi
- Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology

Open and endoscopic Gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-Bleeding Ulcers
- Pancreatitas
- Haemorrhoids
- Cholecystectomy

- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Arthroscopy

Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:

- Ligament and tendon Release
- Contouring and sculpting of articular surfaces
- Capsulectomy in the Knee
- Chondreplasty in the Knee
- Debridement of inflamed synovial tissue
- Chondromalacia Ablation
- Chondromalacia and tears
- Plica Removal
- Meniscectomy
- Loose Body Debridement
- Lateral retinecular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

- Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Foraminoplasty
- Percutaneous Cervical Disc Decompression/Discectomy
- Percutaneous Thoracic Disc Decompression/Discectomy

Gynaecology

Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and cartilage) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

General Surgery

Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Appendectomy
- Skin incision
- Excision of external and internal lesions
- Complete or partial resection of internal organs, tumors and lesions
- Biopsy

5 Non-clinical tests

The present device was subject to non-clinical bench testing according to the following standards:

Table 2: Applied standards.

Standard	Discussion
IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	The present change doesn't affect IEC 60601-1 test reports.
IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.	The present change doesn't affect IEC 60601-1-2 test reports.
IEC 60601-1-6:2010/AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	The present change doesn't affect device usability.
IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices	
IEC 62304:2006/AMD1:2015 Medical device software - Software life cycle processes	SW verification and validation activities have been repeated as the present change involves SW/FW update.
IEC 60601-2-22:2007+AMD1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22 tests have been repeated to check pulse duration accuracy (according to IEC 60601-2-22: 2019).
IEC 60825-1: 2014 Safety of laser products – Part 1: Equipment classification and requirements	The present change doesn't affect IEC 60825-1 report.

The results of the non-clinical performance standards testing support that the subject device can be used safely and effectively.

6 Substantial equivalence discussion

No changes to the intended use have been implemented but a change to laser specifications (pulse width) that are comparable to the ones of the predicate/reference devices as shown in Table 1.

7 Conclusions

Non-clinical tests conducted support that the device can be used safely and effectively. The differences in technological characteristics between the subject and predicate/reference devices do not raise new issues regarding safety and effectiveness (see Table 1). Thus, the subject device is considered substantially equivalent to the predicate/reference devices.

8 Revision history

Rev00: First release.