June 30, 2020

Quanta System Spa
Francesco Dell'antonio
Vice President Regulatory Affairs and QA
Via Acquedotto 109
Samarate (Va), 21017
Italy

Re: K201455
Trade/Device Name: Litho 150, Cyber Ho 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: May 25, 2020
Received: June 1, 2020

Dear Francesco Dell'antonio:

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,

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201455

Device Name
Multicavity Holmium laser

Indications for Use *(Describe)*

The Multicavity Holmium 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 of 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) SUMMARY

Applicant / Manufacturer Name and Address:	Quanta System SPA Via Acquedotto, 109 Samarate (VA) Italy, 21017
510(k) Contact Person:	Francesco Dell'Antonio Vice President Regulatory Affairs and QA Quanta System SPA Email: francesco.dellantonio@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815
Date Prepared:	May 25th 2020
Brand Names:	Litho 150, Cyber Ho 150
Common name:	Multicavity Holmium laser
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 modifications
Predicate Device	Litho 100/60 (K192600) – Quanta System SPA
Reference Device	MultiPulse HoPlus (K161257), Asclepion Laser Technologies Gmbh

The subject device is derived from the legally marketed (predicate) deviced Litho 100 (K192600).

Performance Standards:

There are no mandatory performance standards for this device.

Description of the device:

The devices belonging to Multicavity Holmium laser family are laser devices based on a Holmium laser source.
The main parts (subsystems) of the device are the Holmium laser source, the power electronics, the optical delivery system, the control electronics and the cooling system. A specific software controls the device functions and allows the user selections. Laser emission is triggered by a footswitch.

Description of the modifications:

The device has the same technological characteristics as the predicate device and only differ for maximum power and maximum frequency.

This Special 510(k) is submitted due to Device Modifications of the already cleared device Litho 100 (K192600) due to hardware changes to support a broadening of the range of some laser emission parameters such as power and frequency.

The modified device has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Based on the nature of the changes implemented, the device underwent and successfully passed electrical safety, EMC and performance testing.

	Subject device	**K192600**
Laser Source	Unchanged	-
Laser cavity	Unchanged	-
Technical specifications	Wavelength 2100nm Max energy 5J Max power 152W Max frequency 100Hz	Wavelength 2100nm Max energy 5J Max power 100W Max frequency 80Hz
Software	Same with minor improvement	-
Hardware	4 laser cavities	3 laser cavities
External appearance	Unchanged	-
Graphic user interface	Unchanged	-
Virtual basket mode	present	present

Summary of the technological characteristics

	Subject device	**predicate device**	**additional reference device**
510(k)	-	K192600	K161257
model name	Litho 150, Cyber Ho 150	Litho 100, Cyber Ho 100	MultiPulse HoPlus
manufacturer	Quanta System SpA	Quanta System SpA	Asclepion Laser Technologies Gmbh
Laser Source	Pulsed Holmium laser (CHT:YAG)	Pulsed Holmium laser (CHT:YAG)	Pulsed Holmium laser (CHT:YAG)
Wavelength (nm)	2.1 µm	2.1 µm	2.1 µm

Emission	pulsed	pulsed	pulsed
Pulse duration	up to 1100 µs	up to 1100 µs	up to 1700 µs
Energy per pulse	up to 5.0 Joule	up to 5.0 Joule	up to 6.0 J
Frequency	up to 100 Hz	up to 80 Hz	from 5 to 100 Hz
Max average power	152W	105 W	140 W
Pulse modulation mode	Virtual basket mode	Virtual basket mode	N/A
Delivery system	Optical fibers	Optical fibers	Optical fibers
Aiming beam	Green diode laser < 5 mW	Green diode laser < 5 mW	Green diode laser < 5 mW

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- Skin incision
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Accessories

This device is intended to be used together with delivery optical fiber that separately received a FDA clearance for an intended use compatible with the one of this device.

Performance testing

The subject device was subject to testing according to the following recognized consensus standards related to electromagnetic compatibility, electrical safety and performances.

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

- IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

- IEC 60601-2-22: 2012-10 ed 3.1, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment

- IEC 60825-1 Ed. 3.0 (2014) Safety of laser products – Part 1: Equipment classification and requirements

The following testing were performed on the modified device:

- Software Verification and Validation Testing: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Comparison with predicate device:

The subject and unmodified devices have the same intended use and the same fundamental scientific technology, based on Holmium laser sources.

Summary

The subject device is substantially equivalent to its identified predicate device.