DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2017

Quanta System SPA
Francesco Dell' Antonio
Vice President Regulatory Affairs and QA
Via Acquedotto, 109
Samarate (VA), Italy 21017

Re: K172025
Trade/Device Name: Litho 60
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 27, 2017
Received: July 5, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172025

Device Name
litho 60

Indications for Use *(Describe)*
LITHO 60 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 (BHP),
• 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. Special 510(K) SUMMARY – Device Modifications

Introduction:

This document contains the 510(k) Summary for the device Litho 60.
The basis of this submission is Modifications to a Device already cleared.
The content of this summary is based on the requirements of 21 CFR 807.92(c).

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:	June 27th 2017
Device Name:	Litho 60
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
Legally Marketed Device	Cyber Ho (K170331) – Quanta System SPA

Performance Standards:

There are no mandatory performance standards for this device.

Description of the modifications:

This Special 510(k) of the modified device Litho 60 is submitted due to Device Modifications of the already cleared device Cyber Ho (K170331) due to some technical changes.

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 performance testing and software verifications and validation according to the relevant standards.

Intended Use/Indications for Use

The modified device Litho 60 has the same intended use of the unmodified device, as follows:

LITHO 60 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>

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- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
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- Skin incision
- Excision of external and internal lesions
- Complete of partial resection of internal organs, tumors and lesions
- Biopsy

Substantial Equivalence:

The modified and unmodified devices have the same intended use and the same fundamental scientific technology, based on Holmium laser sources, thus the modified device Litho 60 is substantially equivalent to its identified predicate devices.

Performace testing

The modified device Litho 60 was subjected to performance testing in accordance with the following recognized consensus standards:

IEC 60601-2-22:2007+ A1:2012 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 modified device Litho 60 passed all the required testing and is in compliance will all applicable sections of the above mentioned performance standards.