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

Re: K200234
Trade/Device Name: Surgical laser fibers
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: January 15, 2020
Received: January 30, 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 and Part 809); 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,

Jessica Mavadia-Shukla, Ph.D.
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)*
K200234

Device Name
Surgical Laser Fibers

Indications for Use *(Describe)*
Surgical Laser fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/ certified surgical laser with operational wavelengths between 500nm – 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

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

SUBMITTER:

Manufacturer Name and Address:	Quanta System SPA Via Acquedotto, 109 21017, Samarate (VA) Italy
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:	January 15th 2020

DEVICE:

Device Name:	Surgical Laser Fibers
Common Name:	Surgical Laser Fibers
Regulatory Class:	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:	change to labeling information, product modification

PREDICATE DEVICE:

Primary predicate device	Laser Peripherals Family of Laser Fibers (K170366), Laser Peripherals, LLC
Reference Predicate (unmodified) device	Quanta System Surgical Laser fibers (K160513), Quanta System SpA

The subject device Surgical Laser Fibers is derived from the legally marketed devices Quanta System Surgical Laser fibers (K160513) and Laser Peripherals Family of Laser Fibers (K170366).

DESCRIPTION OF THE DEVICE:

The Surgical Laser Fibers are a Fiber Optic Laser Delivery System meaning a device intended for the delivery of laser radiation to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes and cystoscopes.

The Surgical Laser Fibers are surgical fiber optic laser delivery devices based on a silica core/silica clad fiber. These devices are typically jacketed with ETFE, but some models are characterized by the presence of Nylon coating. The devices are 3.0 meters (9.8 ft) or 5.0 meters (16.4 ft) long and are terminated with a laser specific SMA 905 connector plus a strain relief on the proximal end. Different distal tip configurations and several core diameter sizes (from 200 to 1000 microns) are offered.

DESCRIPTION OF THE MODIFICATIONS:

The subject device intended use is a sub-set of the intended use of the Reference predicate (UNMODIFIED) device, with a simplified wording and no significant difference, based on the intended use of the Primary predicate device.

The subject device has the same technological characteristics (design, material, specifications) as the predicate devices except for the differences shown in the table below.

	Primary predicate device (K170366)	Reference predicate (UNMODIFIED) device (K160513)	Subject modified device
Diameter of core [µm]	150 to 1000	200 to 1000	200 to 1000
Length	3 m	3 m	3 m or 5 m
Connector	SMA 905	SMA 905	SMA 905
Patient contacting materials	ETFE, Polymide	ETFE	ETFE or Nylon
Provided STERILE	Yes (EtO)	Yes (EtO)	Yes (EtO)
Number of Uses	Single Use or Reusable	Single use or re-usable 10x	Single use or re-usable 10x

Based on the nature of the changes implemented, the subject device underwent and successfully passed performance testing according to the relevant standards.

The subject device differs from the unmodified device due to the addition of fibers 5.0 meters long and to the addition of nylon jacketed fibers. These changes can be considered as minor since they do not imply any safety or effectiveness questions, considering the performance verification performed.

INDICATIONS FOR USE

Surgical Laser fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelengths between 500nm – 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

PERFORMANCE DATA:

Same as the Reference predicate device, the Surgical Laser fibers devices comply with the applicable recognized consensus standards.

Performance Standards:
There are no mandatory performance standards for this device.

Bench testing:

Due to the product modifications, the device was subject and successfully passed biocompatibility testing, reprocessing validation testing and initial EtO validation testing according to the following consensus standards:

- ISO 10993-1
- ISO 17664
- ISO 11135

COMPARISON WITH PREDICATE DEVICE:

Even though the intended use is expressed in a simplified wording, it has the same substantial meaning of the reference predicate (unmodified) device (K160513) and it is mainly supported by the Primary predicate device (K170366).

The technical changes do not change the basic physical features and characteristic of the device in a way that any concern could raise about safety and efficacy.

The working principle of the subject devices bases on the same fundamental scientific technology of the main predicate device.

SUMMARY

The subject device Surgical Laser fibers is substantially equivalent to its identified predicate devices.