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

March 18, 2016

Quanta System SPA
Francesco Dell'antonio
Head of Regulatory Affairs
Via IV Novembre, 116
Solbiate Olona (VA), 21058 IT

Re: K160513
Trade/Device Name: Quanta System 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: February 11, 2016
Received: February 24, 2016

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 yours,

Jennifer R. Stevenson -A

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)*
K160513

Device Name
Quanta System Surgical Laser Fibers

Indications for Use *(Describe)*

Quanta System Surgical Laser Fibers are intended to be used in conjunction with any cleared surgical laser manufactured by Quanta System equipped with SMA 905 or SMA 906 or compatible connector.

Quanta System Surgical Laser Fibers are indicated for use in general surgical applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non-contact mode (with a compatible laser marketed for use in the desired application). ·

Quanta System Surgical Laser Fibers (surgical fiber optic laser delivery devices) are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/ otolaryngology, endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with an approved compatible laser marketed for use in the desired application.

Quanta System Surgical Laser Fibers are also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated with an approved compatible laser marketed for use in the desired application.

Quanta System Surgical Laser Fibers are also intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue with an approved compatible laser marketed for use in the desired application.

Quanta System Surgical Laser Fibers are also indicated for use in lithotripsy with an approved compatible laser marketed for use in the desired application.

Quanta System Surgical Laser Fibers are indicated for use with laser devices emitting radiation from 532 nm to 2100 om, with pulsed and continuous wave (CW) emission mode.

Quanta System Surgical Laser Fibers are indicated, but not limited, for use with Diode laser, Argon, KTP/532, Ho;YAG, Nd;YAG, Tm:YAG pulsed and continuous wave CW laser devices.

Quanta System Surgical Laser Fibers may be used in surgical specialty or procedures for which compatible lasers have received regulatory clearance: for a complete information about applications, contraindications, precautions and warnings when using fiber optic it is necessary to refer to the applicable laser device User Manual.

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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5. SPECIAL SIO{K) SUMMARY- DEVICE MODIFICATIONS

Introduction:

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

Applicant/ Manufacturer Name and Address:	Quanta System SPA Via IV Novembre;116 Solbiate Olona (VA) Italy, 21058
SlO{k) Contact Person:	Francesco Dell'Antonio Head of Regulatory Affairs Quanta System SPA Email: francesco.dellantonio@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815
Date Prepared:	February 12 2016
Device Name:	Surgical laser fibers
Classification:	Class II
Classification Name:	laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21CFR 878.4810
Product Code:	GEX
Basis for Submission:	change to labeling information
Ident. of the legally marketed devices	Surgical laser fibers (K131473). The modified device Surgical Laser fibers is claimed to be derived from the legally marketed (unmodified) device Surgical Laser fibers (K131473).
Performance Standards:	There are no mandatory performance standards for this device.
Description of the device:	The Description of the modified device and the unmodified device are exactly the same, as follows. The Quanta System Surgical Laser Fibers are a family of medical devices.

The Quanta System 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 Quanta System Surgical Laser Fibers are surgical fiber optic laser delivery devices based on a silica core/silica clad fiber jacketed with ethylene tetraffluoroethylene (ETFE). The devices are 3.0 meters (9.8 ft) in length and are terminated with a laser specific SMA 905 connector plus a strain relief on the proximal end. Different distal tip configurations and various core diameter sizes (150, 200, 272, 365, 400, 550, 600, 800 and 1000 microns) are offered.

Description of the modifications:

The difference between modified and unmodified devices is limited to the labeling information regarding reprocessing instructions.

Intended use

The intended use and the indications for use of the modified device and the unmodified device are exactly the same, as follows.

Quanta System Surgical Laser Fibers are intended to be used in conjunction with any cleared surgical laser manufactured by Quanta System equipped with SMA 905 or SMA 906 or compatible connector.

Quanta System Surgical Laser Fibers are indicated for use in general surgical applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non-contact mode (with a compatible laser marketed for use in the desired application).

Quanta System Surgical Laser Fibers (surgical fiber optic laser delivery devices) are indicated for use in general surgery urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/otolaryngology, endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with an approved compatible laser marketed for use in the desired application.

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Quanta System Surgical Laser Fibers are indicated for use with laser devices emitting radiation from 532 nm to 2100 nm, with pulsed and continuous wave (CW) emission mode.

Quanta System Surgical Laser Fibers are indicated, but not limited, for use with Diode laser, Argon, KTP/532, Ho;YAG, Nd;YAG, Tm:YAG pulsed and continuous wave CW laser devices.

Quanta System Surgical Laser Fibers may be used in surgical specialty or procedures for which compatible lasers have received regulatory clearance: for a complete information about applications, contraindications, precautions and warnings when using fiber optic it is necessary to refer to the applicable laser device User Manual.

Performance data:

In addition to the performance data provided for the unmodified device (K131473), the modified device reprocessing instructions have been validated.

Biocompatibility:

The materials of the modified and unmodified device have no differences that affect biocompatibility.

Substantial Equivalence:

The modified Surgical Laser fibers has the same intended use, the same indications for use and the same fundamental scientific technology as the unmodified Surgical Laser fibers (K131473).

Quanta System Surgical Laser Fibers have the same components and the same technological characteristics -as the predicate devices. The fiber core and cladding are made from silica which is the same material used in all the predicate devices. The fiber is jacketed with ethylene tetraffluoroethylene (ETFE) which is the same patient-contacting material used in all the predicate devices.

Quanta System Surgical Laser Fibers do not have any technological difference compared to predicate devices.

Quanta System Surgical Laser Fibers have the same intended use as the predicate devices.

Nonclinical performance tests demonstrate that the modified device is as safe and effective as the unmodified device.

Thus Quanta System Surgical Laser Fibers are substantially equivalent to the legally marketed predicate devices