February 14, 2018

Quanta System SPA
Francesco Dell'Antonio
Vice President Regulatory Affairs and QA
via acquedotto 109
Samarate (Va), 21017 Italy

Re: K180158
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 8, 2018
Received: January 19, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K180158

Device Name
EMPOWER Sterile Surgical Optical Fiber

Indications for Use *(Describe)*
Surgical Laser Fibers are intended to be used in conjunction with cleared surgical lasers equipped with SMA 905 or SMA 906 or compatible connector.
Surgical Laser Fibers are indicated for use in general surgical applications for: incision, excision, vaporization, ablation, haemostasis or coagulation of soft tissue in a contact or non-contact mode (with a compatible laser marketed for use in the desired application).
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.
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.
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.
Surgical Laser Fibers are also indicated for use in lithotripsy with an approved compatible laser marketed for use in the desired application.
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.
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.
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)

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.

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"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:	January 8th 2018
Trade Name:	EMPOWER Sterile Surgical Optical Fiber
Common Name:	Sterile Surgical Optical Fiber
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:	change to labeling information
Primary predicate device	Surgical Laser fibers (K160513), Quanta System SpA

The modified device Surgical Laser fibers is derived from the legally marketed (unmodified) device Surgical Laser fibers (K160513).

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 is exactly the same, as follows.
The Surgical Laser Fibers are a Fiber Optic Laser Delivery System meaning a device intended for the delivery of laser radiation to soft tissue.

The Surgical Laser Fibers are surgical fiber optic laser delivery devices based on a silica core/silica clad fiber jacketed with ethylene tetrafluoroethylene (ETFE). The devices are 3.0 meters (9.8 ft) long and are terminated with a laser specific SMA 905 connector plus a strain relief on the proximal end. Different distal tip configurations (flat and ball shaped) and several core diameter sizes (from 200 to 1000 microns) are offered.

Intended use

Surgical Laser Fibers are intended to be used in conjunction with cleared surgical lasers equipped with SMA 905 or SMA 906 or compatible connector.
Surgical Laser Fibers are indicated for use in general surgical applications for: incision, excision, vaporization, ablation, haemostasis or coagulation of soft tissue in a contact or non-contact mode (with a compatible laser marketed for use in the desired application).
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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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.

The wording differs from the one of the predicate device (K160513) limitedly to the removal of the restriction of use with Quanta System laser devices.

Performance data:
Same as the unmodified device, the Surgical Laser fibers devices comply with the following recognized consensus standards:

EN 556-1:2001/AC:2006 Sterilization of medical devices –Requirements for medical devices to be designated "STERILE" – Part 1: requirements for terminally sterilized medical devices.

ISO 15223-1:2012Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

EN 1041:2008 Information supplied by the manufacturer of medical devices.

ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.

ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity.

ISO 11135-1:2007 Sterilization of health-care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization processes for medical devices.

ISO 11138-2:2006 Sterilization of health-care products – Biological indicators – Part 2: biological indicators for moist heat sterilization processes .

ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems.

ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: validation requirements for forming, sealing and assembly processes.

ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorgamisms on product.

ISO 14971:2007 Medical devices - Application of risk management to medical devices.

IEC 61754-22:2005 Fibre optics connector interfaces – Part 22: type SMA connector family.

EN ISO 17665:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Biocompatibility:

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

Comparison with predicate device:

The subject device and its predicate (K160513) have the same intended use and the same technological characteristics.

Any minor differences to the labeling do not present any new types of safety or effectiveness questions.

Summary

Surgical Laser Fibers are substantially equivalent to the legally marketed predicate device (K160513).