K131473

7. Traditional 510(k) SUMMARY

Introduction:

This document contains the 510(k) Summary for the Quanta System Surgical Laser Fibers . The content of this summary is based on the requirements of 21 CFR 807.92(c).

Submitter:	Maurizio Bianchi Regulatory Affairs Manager Quanta System SPA Email: Maurizio.bianchi@quantasystem.com regulatory@quantasystem.com.local Phone: +39-0331-376797 Fax: +39-0331-367815
Manufacturer name and street address:	Quanta System SPA Via IV Novembre, 116 Solbiate Olona (VA) Italy, 21058
Establishment Registration Number:	3004378299
Type of Submission:	Traditional 510(k)
Trade Name:	Quanta System Surgical Laser Fibers
Common Name:	Fiber Optic Laser Delivery System
Classification Name:	Surgical Laser Accessory (for Powered Laser Surgical Instrument)
Device Classification:	Class II, 21 CFR 878.4810
Device Classification Panel:	General & Plastic Surgery
Device Product Code:	GEX
Basis for Submission:	New Device

OCT 24 2013

Legally Marketed Device

The Quanta System Surgical Laser Fibers is claimed to be substantially equivalent to these legally marketed devices:

- Laser Peripherals Bare Fibers (K972272)
- Laser Peripherals Reusable Bare Fibers (K011207)
- FiberTech Leoni Bare Fibers (single & reusable) (K050738)
- Lumenis SlimLineEZ Fiber Delivery Device (K011703)
- InnovaQuartz (AMS) Sure Flex Laser Fiber (K050108)
- BioLitec Radial Emitting Fiber Optic Deliv.System (K110080)

- BioLitec MegaBeam Endo-ENT-Probe (K113858)
- BARD Medical Holmium Laser Fibers (K120926)
- Fiberoptic Fabrications Laser Delivery System (K120810)
- Cynosure SideLaze800Side-Fire Laser deliv. Dev. (K121127)
- MED-Fibers Fiber Optics Laser Deliv. System (K124003)

Performance Standards:

There are no mandatory performance standards for this device.

General Device Description:

The Quanta System 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) 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.
The Quanta System Surgical Laser Fibers are single-use sterile medical devices, supplied sterilized by Ethylene Oxide (EtO).

Summary of Performance and basic Safety testing:

A full plan of non-clinical performance tests was conducted in accordance with ISO 14971:2009, ISO 10993-1:2008 and FDA Blue Book Memo G95-1. This plan includes:
- visual, mechanical and functional(optical) tests per internal methods.
- Biocompatibility testing following ISO 10993-1:2008 and FDA Blue Book Memo G95-1.
- First EtO sterilization validation following ISO 11135-1:2007 and FDA Sterility Review Guidance K90
- Packaging validation following ISO 11607-1:2009 and FDA Sterility Review Guidance K90
- Re-processing validation following ISO 17664:2004 and FDA MDUFMA Validation Data in 510(k) for Reprocessed single-use medical device

Intended Use:

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 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.

Substantial Equivalence:

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 tetrafluoroethylene (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 device is safe and effective as the predicate devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quanta System SPA
Mr. Maurizio Bianchi
Regulatory Affairs Manager
Via IV Novembre, 116
21058 Solbiate Olana (VA)
Italy

October 24, 2013

Re: K131473
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: September 9, 2013
Received: September 11, 2013

Dear Mr. Bianchi:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131473

Device Name: Quanta System S.P.A Surgical Laser Fibers

Indications For Use:

Quanta Systems 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 connector.

Quanta Systems Surgical Laser Fibers are indicated for use in general surgery 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.

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

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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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden
2013.10.24 15:45:00 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K131473