March 11, 2021

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

Re: K210142
Trade/Device Name: Fiber Dust
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: December 29, 2020
Received: January 19, 2021

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,

Purva Pandya
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210142

Device Name
Fiber Dust

Indications for Use *(Describe)*
Fiber Dust is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
• Laser Resection of the Prostrate (LRP)
• Laser Enucleation of the Prostate (LEP)
• Laser Ablation of the Prostate (LAP)
• Transurethral Incision of the Prostate (TUIP)
• Condylomas
• Urethral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones
• Endoscopic fragmentation of renal 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
• Angiodysplasia
• Polyps
• Colorectal cancer
• Biopsy
• Telangiectasias
• Gall Bladder calculi
• Telangiectasias of the Osler-Weber-Renu disease
• Biliary/Bile duct calculi
• Vascular Malformation
• Ulcers
• Gastritis
• Gastric ulcers
• Esophagitis
• Duodenal ulcers
• Esophageal ulcers

• Non Bleeding Ulcers
• Varices
• Pancreatitis
• Colitis
• Haemorrhoids
• Mallory-Weiss tear
•Cholecystectomy
• Gastric Erosions
•Benign and Malignant Neoplasm

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	4th March 2021
Device Name:	Fiber Dust
Common name:	Surgical laser
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
Predicate Device	SOLTIVE Laser System – Olympus Surgical Technologies America (K183647)

Description of the device:

The Fiber Dust laser device includes a diode laser that emits a wavelength of 1940 nm with a laser output power up to 60W. Laser radiation is delivered to the patient via a quartz optical fiber having a diameter up to 1000 µm.
The main subsystems of the device are the diode laser, the power electronics, the optical delivery system, the control electronics, and the cooling system. Software controls the device functions and allows the user select device settings. Laser emission is triggered by a footswitch.

Summary of the technological characteristics

	Subject device	Predicate device(s)	Comparison to predicate devices
model name	Fiber Dust	SOLTIVE Laser System	-
manufacturer	Quanta System SpA	Olympus Surgical Technologies America	-
510(k)	-	K183647	-
Laser Source	Thulium laser	Thulium laser	Same technology
Wavelength (nm)	1.94 µm	1.94 µm	Same
Emission	CW/pulsed	CW/pulsed	Same
Pulse duration	0.1 to 15ms	0.2 to 50ms	Within the range of the predicate
Pulse energy	0.02 to 6J	0.025 to 6J	Within the range of the predicate
Frequency	1 to 2500 Hz	1 to 2400 Hz	Similar
Max average power	60 W	60 W	Same
Delivery system	Optical fibers	Optical fibers	Same as
Aiming beam	532nm laser < 5 mW	500-550nm laser < 5 mW	Equivalent
Cooling system	Air cooling system	Air cooling system	Equivalent

Indications for Use

Fiber Dust is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

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• Biliary/Bile duct calculi
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• Gastritis
• Gastric ulcers
• Esophagitis
• Duodenal ulcers
• Esophageal ulcers
• Non Bleeding Ulcers
• Varices
• Pancreatitis
• Colitis
• Haemorrhoids
• Mallory-Weiss tear
•Cholecystectomy
• Gastric Erosions
•Benign and Malignant Neoplasm

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

Accessories

This device is intended to be used together with delivery optical fiber that separately received an FDA clearance for an intended use compatible with the one of this device.

Performance testing

The subject device was subject to testing according to the following recognized consensus standards related to electromagnetic compatibility, electrical safety and performances.

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance

- IEC 60601-1-2:2014, ed 4, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.

- IEC 60601-2-22: 2012, ed 3.1, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment

- IEC 60825-1:2014, ed 3.0, Safety of laser products – Part 1: Equipment classification and requirements

- IEC60601-1-6:2013, ed 3.1, Medical Electrical Equipment Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

- Software Verification and Validation Testing: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The results of the non-clinical performance standards testing support that the device can be used safely and effectively.

Comparison with predicate device:

The subject device's technological characteristics and indications for use are similar to the predicate device, and its laser output ranges are equivalent to those of the predicate device. Other differences between the subject and predicate device to not raise new types of questions regarding the subject device's safety and efficacy.

Conclusions

The non-clinical performance testing conducted supports that the device can be used safely and effectively. The differences in the indications for use and technological characteristics between the subject and predicate device do not raise new types of questions regarding safety and effectiveness, and the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.