March 16, 2022

Quanta System Spa
Dario Bandiera
RA Manager
Via Acquedotto, 109
Samarate, 21017
Italy

Re: K220426
Trade/Device Name: Fiber Dust PRO
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 7, 2022
Received: February 14, 2022

Dear Dario Bandiera:

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); 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)*
K220426

Device Name
Fiber Dust PRO

Indications for Use *(Describe)*
Fiber Dust PRO 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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510(K) SUMMARY

Applicant / Manufacturer Name and Address:	Quanta System S.p.A. Via Acquedotto, 109 Samarate (VA) Italy, 21017
510(k) Contact Person:	Dario Bandiera Regulatory Affairs Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815
Date Prepared:	7th February 2022
Trade Name:	Fiber Dust PRO
Device:	Powered Laser Surgical Instrument
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:	Addition of a new model
Predicate Device	FiberDust – Quanta System S.p.A. (K210142)

Description of the device:

Fiber Dust PRO is a laser system 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 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.

Device comparison

The proposed modified version is a mobile console configuration and the predicate device is a desktop configuration.
Technical specifications are the same or similar

	Proposed device	Predicate device	Comparison to predicate device
model name	Fiber Dust PRO	Fiber Dust	-
manufacturer	Quanta System S.p.A.	Quanta System S.p.A.	-
510(k)	-	K210142	-
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	Up to 15ms	Up to 15ms	Same
Frequency	Up to 2500 Hz	Up to 2500 Hz	Same
Max average power	60 W	60 W	Same
Configuration	Mobile	Desktop	Conformance with IEC 60601-1 and IEC 60601-1-2 performance standards
Delivery system	Optical fibers	Optical fibers	Same
Aiming beam	532nm laser < 5 mW	532nm laser < 5 mW	Same

Intended use

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

Fiber Dust PRO 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]
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- Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
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- Telangiectasias
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- 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

Performance data:

Based on the nature of the modification, the modified device was subjected to performance testing in accordance with the following recognized consensus standards:

- IEC 60601-1:2005 MOD Medical Electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The modified device passed all the required testing and is in compliance will all applicable sections of the above mentioned performance standards.

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".

Biocompatibility:

There are no new patient-contacting materials used in the K210142 device compared to those used in the Fiber Dust PRO device that adversely affect biocompatibility.

Substantial Equivalence:

The modifications made to produce the Fiber Dust PRO do not raise new types of questions regarding the safety and effectiveness of the device for the proposed indications for use, and the performance testing supports that the device can be used safely and effectively for the proposed indications for use. The device is considered to be substantially equivalent to the predicate device K210142.