October 17, 2017

Quanta System S.p.A.
Francesco Dell'antonio
V.P. Regulatory Affairs and Quality Assurance
Via Acquedotto, 109
Samarate, 21017 It

Re: K172198
Trade/Device Name: 585
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: July 10, 2017
Received: July 21, 2017

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 (DICE) 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 (DICE) 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,

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)*
K172198

Device Name
585

Indications for Use *(Describe)*
The device is intended for treatment of benign vascular and benign pigmented lesions.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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

Introduction:

This document contains the 510(k) Summary for the 585.
The content of this summary is based on the requirements of 21 CFR 807.92(c).

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:	July 10th 2017
Device Name:	585
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 Devices:

585 is substantially equivalent to the following legally marketed predicate devices:

- Main predicate device: QuadroStarPRO (K133297), Asclepion Laser Technologies GmbH
- Additional Predicate device: YellowStar (K013940), Asclepion Laser Technologies GmbH

Description of the device:

585 is a diode laser device used mainly for dermatology.
It includes a main panel with the touch screen display, the optical fiber connector (SMA 905) and the status LEDs. On the rear panel the connectors for footswitch, remote interlock and power supply cable are located. The key switch and the emergency knob are located on the upper part of the device.
The laser system is composed of an opto-mechanical block containing the laser source and heat dissipation system, aiming beam, control system and power electronics.
The power electrical system is composed of a power supply. The control electronics, based on a microcontroller, manages power electronics, thermalization of the laser source and controls the user interface.

Emission is triggered by means of a footswitch.

Intended use

The device is intended for treatment of benign vascular and benign pigmented lesions.

Performance data:

The following performance data are provided in support of the substantial equivalence determination:

Safety and electromagnetic compatibility (EMC)
Electrical safety and electromagnetic compatibility (EMC) testing for proposed device was conducted by an independent test laboratory in accordance with IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and with IEC 60601-1-2, Collateral
Standard: Electromagnetic Compatibility - Requirements and Tests, 3rd ed.
585 was determined to be in conformance with applicable IEC standards (IEC 62366, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22, and IEC 60825-1).

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:

The biocompatibility of the proposed device is established based on the predicate devices.

Substantial Equivalence:

585 has the same intended use and the same indications for use as its predicate devices, as it has the same or similar technological characteristics, including the laser type, wavelength, pulse width, frequency and spot size. Any minor differences do not raise any new types of safety or effectiveness questions since the parameters are the same as the predicate devices.

Therefore, 585 is substantially equivalent to its predicate devices.