December 13, 2017

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

Re: K173002
Trade/Device Name: 2940 nm Er:Yag Laser Handpiece
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 18, 2017
Received: September 27, 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.

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)*
K173002

Device Name
2940 nm Er:Yag Laser Handpiece

Indications for Use *(Describe)*
2940 nm Er:Yag Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).
With microbeam end piece it is indicated for Skin resurfacing.

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
PRAStaff@fda.hhs.gov

"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 2940 nm Er:YAG handpiece.
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 V.P. Regulatory Affairs and Quality Assurance Quanta System S.p.A. Email: francesco.dellantonio@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815

Date Prepared:	12/11/2017
Device Name:	2940 nm Er:YAG laser handpiece
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:

The modified device 2940nm Er:YAG handpiece is derived from the legally marketed (unmodified) device 2940nm handpiece cleared under Quanta Forte platform (K152714).

2940nm Er:YAG handpiece is substantially equivalent to the following legally marketed predicate devices:

- Primary predicate: K152714 Quanta Forte - QUANTA SYSTEM SPA
  Additional predicate:
- K132806 FOTONA F-22 LASER HANDPIECE, FOTONA FS-01 LASER HANDPIECE - FOTONA D.D.
- K152153 MicroSpot Handpiece - ASCLEPION LASER TECHNOLOGIES GMBH

Performance Standards:
There are no mandatory performance standards for this device.

Description of the device:
2940nm Er:YAG handpiece is the same as the one cleared with Quanta Forte platform (K152714), with the addition of a microbeam end piece.

2940nm Er:YAG is an handpiece that can work in conjunction with Quanta System FDA cleared devices (Quanta Forte and EVO and Discovery Pico Platform) provided with a suitable connector for recognizing and controlling the handpiece.

Its emission is triggered by means of a footswitch connected to the console of the device it is used with.

Intended use

2940 nm Er:Yag Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).
With microbeam end piece it is indicated for Skin resurfacing.

Summary of technological similarities and differences of the new device in comparison with the predicate

Specifications	Subjected device	Original (unmodified device)	additional predicate device	
Trade/ Device Name	2940 nm Er:YAG Laser Handpiece	Quanta Forte	Fotona F-22/FS-01 Laser Handpiece (F-RUNNER)	MicroSpot Handpiece
510(K) #	-	K152714	K132806	K152153
Submitter	Quanta System S.p.A.	Quanta System S.p.A.	FOTONA D.D.	Asclepion Laser Technologies GmbH
Laser medium	Er:YAG	Er:YAG	Er:YAG	Er:YAG
Wavelength [nm]	2940	2940	2940	2940
Energy, max [J]	3	3	3	2.5
Fluence [J/cm^2]	Up to 95 (non microbeam mode); Up to 121 (with stacking pulses – microbeam mode)	Up to 95 (non microbeam mode);	Up to 300 (stacking pulses – microbeam mode)	Up to 51 (stacking pulses – microbeam mode with 600 µm dots) Up to 150 (stacking pulses – microbeam mode with 300 µm dots)
Pulse duration [ms]	0.3 to 1.5 ms	1 to 1.5 ms	0.1 to 1.5 ms	0.1 -1.0 ms
Repetition rate, max [Hz]	6	5	50	20
Spot size	Ø 2, 4, 9mm Ø 9mm dots array	Ø 2, 4, 9mm	13x13 mm dots array	13x13 mm dots array

Performance data:

The following performance data are provided in support of the substantial equivalence determination, for the Er:YAG handpiece used in conjunction with the devices it is intended to be used with.

Safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Quanta Forte device.
The system complies with the IEC 60601-1, IEC 60601-2-22 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
The Er:YAG handpiece does not contain any software, as it is controlled by the software of the devices it is used in conjunction with (already FDA cleared). Those software were not modified due to the use with the microbeam Er:YAG handpiece.
They successfully underwent verification and validation testing 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".

Histological performance data are provided to demonstrate substantially equivalent skin resurfacing effects to its predicate devices with a microlens array.

Biocompatibility:

The biocompatibility of the Er:YAG handpiece is established based on the predicate devices.

Conclusion:

The subject device is comparable to its primary predicate and the additional predicate devices as it has similar intended use and core fundamental technology as show in the SE table above.

Therefore, Er:YAG handpiece is substantially equivalent to its identified predicate devices.