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

December 5, 2016

Quanta System Spa
Francesco Dell'antonio
Vice President Regulatory Affairs And Quality Assurance
Via Acquedotto, 109
Samarate, 21017 IT

Re: K163222
Trade/Device Name: Discovery Pico Family
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: November 4, 2016
Received: November 16, 2016

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 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 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 -A

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)*
K163222

Device Name
Discovery Pico Family

Indications for Use *(Describe)*
General intended use

The Discovery Pico Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.

Indications for use

1064 & 532 nm (Q-Switched, nanosecond mode)
The Discovery Pico Family is intended for treatment of vascular lesions, pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of:

532 nm (Q-Switched, nanosecond mode)
Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos
Treatment of vascular lesions including, but not limited to:
- port wine birthmarks
- telangiectasias
- spider angiomaa
- Cherry angioma
- Spider nevi

Treatment of benign pigmented lesions including, but not limited to:
- cafe-au-Iait birthmarks
- Ephalides, solar lentigines
- senile lentigines
- Becker's nevi
- freckles
- common nevi
- nevus spilus
- Ota Nevus

Treatment of seborrheic keratosis
Treatment of post inflammatory hyperpigmentation
Skin resurfacing procedures for the treatment of acne scars and wrinkles.

1064 nm (Q-Switched, nanosecond mode)
Removal of dark ink (black, blue and brown) tattoos
Removal of benign pigmented lesions including;
- nevus of Ota
- Café au lait spot
- Ephalides, solar lentigo (lentigines)
- Becker Nevus
- Nevus spilus

Treatment of common nevi

Removal or lightening of unwanted hair
Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064 nm (non Q-Switched – free running mode)
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin.
Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins.
Coagulation and hemostasis of soft tissue.
Treatment of wrinkles.
Treatment of mild to moderate inflammatory acne vulgaris.

532 nm (picosecond mode)
Indicated for the removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.

1064 nm (picosecond mode)
Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.

694 nm (Q-Switched)

Indicated for:
Tattoo removal: Suggested for blue, sky blue, black, green and violet ink
Pigmented lesion removal (benign):
- Cafe au lait spot
- Ephalides, solar lentigo lentigines)
- Becker Nevus
- Ota and Ito Nevus
- Nevus spilus
- Mongolian spot

694 nm (non q-switch – free running mode)

Intended to remove benign dermal and epidermal pigmented lesions, and, to effect hair removal of patients with skin types 1-4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery.

IPL 590-1200nm; 625-1200nm; 650-1200nm
Indicated for permanent hair removal.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime

IPL 550-1200nm; 570-1200nm

Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.

IPL 400-1200nm

Indicated for inflammatory acne (acne vulgaris).

Integrated Skin Cooler
The intended use of the integrated cooling system in the laser hand piece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluencies for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments. Any other different use is considered incorrect.

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.

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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. SPECIAL 510(K) SUMMARY – DEVICE MODIFICATIONS

Introduction:

This document contains the 510(k) Summary for the Discovery Pico Family.
The basis of this submission is Modifications to Device already cleared.
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:	November 4th , 2016
Device Name:	Discovery Pico Family
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:	change to performance specifications
Ident. of the legally marketed devices	EVO Platform (K160368), Quanta System SpA

The modified device Discovery Pico Family is claimed to be derived from the legally marketed (unmodified) device EVO Platform (K160368).

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

Description of the device:

The Description of the modified device and the unmodified device are exactly the same; the modified device is a subset of the unmodified device in terms of available laser sources:
The differences are shown in the table below:

The Discovery Pico Family is a laser family that includes Q-Switched and/or Pulsed laser sources, emitting at one or more of the following wavelengths: 532 nm, 1064 nm, 694 nm (Ruby laser)
The Discovery Pico Family systems, through the special universal Twain connector, can be equipped with intense pulsed light handpieces (Twain IPL) emitting at the following wavelengths: 650-1200nm, 625-1200nm, 590-1200nm, 570-1200nm, 550-1200nm, 400-1200nm.
The Discovery Pico Family systems, when operating with Pulsed laser sources and IPL, can be used in combination with optional contact, or air, cooling systems.
The optical delivery system is an articulated arm with fixed handpieces. The optical delivery system for the IPL system is a handpiece (Twain IPL) with fixed or interchangeable light filters at different wavelengths.

All the models belonging to the Discovery Pico Family have the same components and the same control software. The only difference between different models is the optical bench that depends on the sources installed.

The Discovery Pico Family is controlled via a touch screen display housed in the front of the device.

Emission is triggered by means of a footswitch.

Description of the modifications:

The difference between modified and unmodified devices is limited to the laser emission tuning, thus producing a change to some performance specifications.

Intended use

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

General intended use

The Discovery Pico Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.

Indications for use

1064 & 532 nm (Q-Switched, nanosecond mode)
The Discovery Pico Family is intended for treatment of vascular lesions, pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of:

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- telangiectasias
- spider angiomaa
- Cherry angioma
- Spider nevi

Treatment of benign pigmented lesions including, but not limited to:

- cafe-au-Iait birthmarks
- Ephalides, solar lentigines
- senile lentigines
- Becker's nevi
- freckles
- common nevi
- nevus spilus
- Ota Nevus

Treatment of seborrheic keratosis
Treatment of post inflammatory hyperpigmentation
Skin resurfacing procedures for the treatment of acne scars and wrinkles.

1064 nm (Q-Switched, nanosecond mode)
Removal of dark ink (black, blue and brown) tattoos
Removal of benign pigmented lesions including;

- nevus of Ota
- Café au lait spot
- Ephalides, solar lentigo (lentigines)
- Becker Nevus
- Nevus spilus

Treatment of common nevi
Removal or lightening of unwanted hair
Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064 nm (non Q-Switched – free running mode)
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin.
Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins.
Coagulation and hemostasis of soft tissue.
Treatment of wrinkles.
Treatment of mild to moderate inflammatory acne vulgaris.

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Indicated for the removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.

1064 nm (picosecond mode)
Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.

694 nm (Q-Switched)

Indicated for:
Tattoo removal: Suggested for blue, sky blue, black, green and violet ink
Pigmented lesion removal (benign):

- Cafe au lait spot
- Ephalides, solar lentigo lentigines)
- Becker Nevus
- Ota and Ito Nevus
- Nevus spilus
- Mongolian spot

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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 60601-2-22 Third Edition 2007-05, 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 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements

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

Both the modified and unmodified device also comply with the following standards:

Safety and electromagnetic compatibility (EMC)

- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

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 materials of the modified and unmodified device have no differences.

The biocompatibility of the Discovery Pico Family is established based on the predicate devices.

Thermal performance

The maximum fluence of the subject device is the same as the predicate device.

Substantial Equivalence:

The modified Discovery Pico Family has the same intended use, the same indications for use and the same fundamental scientific technology as the unmodified EVO Platform (K160368).

The performance specification of modified Discovery Pico Family are the same as the unmodified EVO Platform (K160368), except for some laser parameters, which do not present different concerns of safety and effectiveness, as the maximum fluence is not changed.

Therefore, the Discovery Pico Family is substantially equivalent to the unmodified EVO Platform (K160368).