



September 17, 2019

Quanta System, S.p.A.
Francesco Dell'Antonio
V.P. Regulatory Affairs & Quality Assurance
Via Acquedotto, 109
Samarate, IT 20826 VA

Re: K191842

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: June 27, 2019

Received: July 9, 2019

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); 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
Acting 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

510(k) Number (if known)
K191842

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 benign vascular lesions, benign 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), including microbeam handpieces:

Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos

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

- port wine birthmarks
- telangiectasias
- spider angiomas
- Cherry angioma
- Spider nevi

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

- cafe-au-lait 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), including microbeam handpieces:

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 benign pigmented and benign vascular lesions, such as, but not limited to port wine stains, hemaangiomae, 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) , also with fractional and microbeam handpieces:

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.

Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

1064 nm (picosecond mode), also with fractional and microbeam handpieces:

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.

Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

Only with fractional handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V

694 nm (Q-Switched), including microbeam handpieces

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 benign 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 (mild to moderate 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 benign 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.

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
PRASStaff@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.”

K191842

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:

June 27th 2019

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

Predicate device

Discovery Pico Family (K172376), Quanta System SpA

The modified device Discovery Pico Family is derived from the legally marketed (unmodified) device Discovery Pico Family (K172376).

Performance Standards:

There are no mandatory performance standards for this device.

Description of the device (unchanged from K172376):

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.

It can also be connected to Er:YAG handpieces cleared under K173002.

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 controlling 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:

This Special 510(k) is submitted due to the adding of microbeam handpieces to the already approved fractional handpieces, as per the table below:

Wavelength	1064nm		532nm		694
	Picosecond	Nanosecond	Picosecond	Nanosecond	Nanosecond
Homogeneous spot handpieces	Already approved	Already approved	Already approved	Already approved	Already approved
Fractional handpiece	Already approved	-	Already approved	-	-
Standard microbeam handpiece	-	new	-	new	new
High coverage microbeam handpiece	new	new	new	new	new

The modified device has the same intended use of the unmodified device. Moreover the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Based on the nature of the changes implemented, the device underwent and successfully passed electrical safety, EMC, performance testing and software verifications and validation according to the relevant standards.

Intended use

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 benign vascular lesions, benign 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), including microbeam handpieces:

Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos

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

- port wine birthmarks
- telangiectasias
- spider angiomas
- Cherry angioma
- Spider nevi

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

- cafe-au-lait 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), including microbeam handpieces:

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 benign pigmented and benign vascular lesions, such as, but not limited to port wine stains, hemaangiomas, 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) , also with fractional and microbeam handpieces:

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.

Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

1064 nm (picosecond mode), also with fractional and microbeam handpieces:

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.

Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

Only with fractional handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V

694 nm (Q-Switched), including microbeam handpieces

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 lentiginos)
- 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 benign 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 (mild to moderate 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 benign vascular lesion, and to reduce the potential side effects of laser treatments. Any other different use is considered incorrect.

Performance data:

Discovery Pico family devices comply 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 3.0: 2014, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements
- 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.
- Thermal-histology performance data for fractional handpieces
- Bench testing measurements were done to confirm the output of microbeam handpieces

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 Discovery Pico Family is established based on the predicate devices.

Comparison with predicate device:

The subject device and its predicate have the same general intended use and technological characteristics.

Any minor differences do not present any new types of safety or effectiveness concerns since the Discovery Pico Family parameters are similar to or within the range of the predicate.

Summary

Testing of the Discovery Pico Family demonstrated that the device performs as intended. The Discovery Pico Family is substantially equivalent to the predicate devices.

