June 6, 2025

Quanta System SpA
Dario Bandiera
Regulatory Affairs Manager
Via Acquedotto 109
Samarate, VA 21017
Italy

Re: K240983
Trade/Device Name: Discovery Pico; Discovery Pico Plus; Discovery Pico Derm
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: May 9, 2025
Received: May 27, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S Digitally signed by TANISHA L. HITHE -S
Date: 2025.06.06 17:57:56 -04'00'

Tanisha Hithe
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)*
K240983

Device Name
Discovery Pico;
Discovery Pico Plus;
Discovery Pico Derm

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 angioma
- 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), 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, 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), 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary # K240983

Applicant / manufacturer:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	24th April 2024
Model name:	Discovery Pico Family including the following models: Discovery Pico, Discovery Pico Plus, Discovery Pico Derm.
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 #1	Enlighten III (K160488) manufactured by Cutera.
Predicate device #2	Discovery Pico family (K191842) manufactured by Quanta System.

1 Abbreviations

FW= firmware
FWHM= full width at half maximum
GUI= graphical user interface
IPL= intense pulsed light
OP= Opti-Pulse
PS= Pico-seconds
PT= Photo-Thermal
QS= Q-Switched
SW= software

2 Device description

General description

Discovery Pico family includes medical laser devices for dermatology and aesthetic medicine. It is used by health care professionals (dermatologists) in professional healthcare environments for the treatment of different skin conditions and hair removal.
Discovery Pico family includes the following models: Discovery Pico, Discovery Pico Plus, Discovery Pico Derm. Discovery Pico models differ for the installed laser sources and the presence of the Twain connector according to Table 1.

Table 1: Discovery Pico family models with installed laser sources.

	Nd: YAG 1064 nm (QS/OP)	Nd: YAG 532 nm (QS/OP)	Nd: YAG 1064 nm (PT)	Ruby 694 nm (QS/PT)	Nd: YAG 1064 nm (PS)	Nd: YAG 532 nm (PS)	Twain connector
Discovery Pico	x	x	x		x	x	x
Discovery Pico Plus	x	x	x	x	x	x	x
Discovery Pico Derm			x		x	x	

The device is equipped with a display with a graphical user interface (GUI) for user-device interaction (e.g. laser parameters settings).
Discovery Pico devices can be used in conjunction with Twain IPL and Twain 2940 devices. Twain 2940 is separately FDA cleared (K173002).
Laser beam is delivered through an articulated arm with handpiece connected at its end and can be activated with a footswitch. Four types of handpieces are available:

- Round (diameter): 2 to 12 mm;
- Square (side): 2, 3, 4, 5, 7 mm;
- Microbeam/fractional handpieces: 8, 9 mm. 9 mm microbeam handpiece is also called “High Coverage”;
- *Rosso* handpiece (separately FDA cleared: K211228).

The device can be divided into four main sections:

- Power electronics: they manage power supplied to all device compartments;
- Control electronics: they mainly consist of a microcontroller board where device main firmware (FW) is resident;
- Cooling system: it cools the laser source pumping chamber and, in case of Twain IPL, IPL flashlamp;
- Optical bench.

Twain IPL

Twain IPL accessory is an intense pulsed light (IPL) optional handpiece intended for hair reduction and treatment of several skin lesions. Twain IPL can be provided cooled or not and with fixed or changeable guides emitting at the following wavelength ranges:

- 650-1200 nm
- 625-1200 nm
- 590-1200 nm
- 570-1200 nm
- 550-1200 nm
- 400-1200 nm

Moreover, each guide is available in two different sizes: small (25x13 mm^2) and large (48x13 mm^2).

VarioPulse

In PS mode, the user can select three different pulse levels corresponding to pulse durations as shown in Table 2. Such configuration where pulse duration in PS is settable by the user is optional and is identified as "VarioPulse" techncology.

Table 2: Pulse durations corresponding to each pulse level.

Pulse	Pulse width at 1064 nm	Pulse width at 532 nm
Short (S)	450 ps	370 ps
Medium (M)	600 ps	500 ps
Long (L)	800 ps	600 ps

3 Comparison with predicates

In the following table (Table 3) the main specifications of the subject device are summarized and compared to the predicate devices:

Table 3: Main specifications comparison table.

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
K number	-	K160488	K191842	-
Manufacturer	Quanta System SpA	Cutera	Quanta System	-
Product Code	GEX	GEX	GEX	-
Laser Sources	Nd:YAG and Ruby	Nd:YAG	Same as the subject device	Same as predicate device #2
Laser Wavelengths (nm)	☒ 1064 QS/OP ☒ 532 QS/OP ☒ 1064 PT ☒ 694 (QS/PT) ☒ 1064 PS ☒ 532 PS ☒ IPL (with Twain connector) ☒ 2940 (with Twain connector)	532 (PS, QS), 670, 1064 (PS, QS)	Same as the subject device	Same as predicate device #2
Indications for 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 angioma	532 nm • Treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III. • Tattoo removal for lighter coloured tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III. 670 nm The 670 nm wavelength of the enlighten III laser system is indicated for treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III. 1064 nm	Same as the subject device	Same as predicate device #2

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
	- 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), 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, 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.	• Treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI). • Tattoo removal for dark coloured tattoo inks and for multi-coloured tattoos containing dark coloured tattoo inks on patients with all skin types (Fitzpatrick I-VI).		

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
	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*			

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
	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.			
Pulse width$_{max}$	@1064 (QS): 6 ns @1064 (OP): 12 ns @1064 (PS): 450-**800** ps @1064 (PT): 250 µs @532 (QS): 6 ns @532 (OP): 12 ns @532 (PS): **370**-**600** ps @694 (QS): 30 ns @694 (PT): 2 ms	@1064 (QS): 2 ns @1064 (PS): **750** ps @532 (QS): 2 ns @ 532 (PS): **750** ps @670 (PS): 660 ps	@1064 (QS): 6 ns @1064 (OP): 12 ns @1064 (PS): **450** ps @1064 (PT): 250 µs @532 (QS): 6 ns @532 (OP): 12 ns @532 (PS): **400** ps @694 (QS): 30 ns @694 (PT): 2 ms	Higher limit @1064 (PS): very similar to predicate device #1 (800 vs 750 ps). @532 (PS): covered by predicate device #1 (600 vs 750 ps). Lower limit @532 (PS): very similar to the predicate device #2 (370 vs 400 ps).
Spot side (for square handpieces) or diameter (for round handpieces) in mm	Square: 2, 3, 4, 5, 7 Round: 2 to 12 Round (microbeam/fractional): 8, 9	Round (@1064, 532 nm): 2, 3, 4, 5, 6, 7, 8 Round (@670 nm): 2, 3, 4, 5, 6	Same as the subject device	Subject device vs predicate device #1 (with homogeneous spots): Maximum spot area of the subject device is higher than the predicate device #1. Not clinically significant parameter (higher treated area). Same as predicate device #2
Repetition rate$_{max}$ (Hz)	@1064, 532 (QS/OP/PS/PT): 10 @694 (QS/PT): 3	10	Same as the subject device	Subject device vs predicate device #1 (with homogeneous spots): @1064 (PS): the same

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
				@532 (PS): subset of the predicate Same as predicate device #2
Energy$_{max}$ (J)	@1064 (QS): 0.8 @1064 (OP): 1.2 @1064 (PS): 0.8 @1064 (PT): 2 @532 (QS): 0.4 @532 (OP): 0.45 @532 (PS): 0.3 @694 (QS): 1.2 @694 (PT): 2	@1064: 0.6 @532: 0.3 @670: 0.125	Same as the subject device	Subject device vs predicate device #1 (with homogeneous spots): @1064 (PS): similar (0.8 vs 0.6) @532 (PS): the same Clinically significant parameter affecting thermal effects is the maximum fluence and not energy. Same as predicate device #2
Fluence$_{max}$ (J/cm^2)	@1064 (QS): 20 @1064 (OP): 30 @1064 (PS): 5.6 @1064 (PT): 50 @532 (QS): 10 @532 (OP): 11.25 @532 (PS): 2.8 @694 (QS): 30 @694 (PT): 25	@1064 nm: 10 @532 nm: 2.5 @670 nm: 4.0	Same as the subject device	Subject device vs predicate device #1 (with homogeneous spots): @1064 (PS): subset (5.6 vs 10) @532 (PS): similar (2.8 vs 2.5) Same as predicate device #2
With fractional handpiece (8 mm)				
Spot overall dimension (mm)	Round 8	-	Same as the subject device	Same as predicate device #2
Energy$_{max}$ (J)	@1064 (PS): 0.73 @532 (PS): 0.3	-	Same as the subject device	Same as predicate device #2
Fluence/dot$_{max}$ (J/cm^2)	@1064 (PS): 18.4 @532 (PS): 8.7	-	Same as the subject device	Same as predicate device #2
Dot diameter (µm)	@1064 (PS): 200 @532 (PS): 165	-	Same as the subject device	Same as predicate device #2
Coverage (%)	@1064 (PS): 4 @532 (PS): 3	-	Same as the subject device	Same as predicate device #2
With microbeam handpiece (9 mm)				
Spot overall dimension (mm)	Round 9	-	Same as the subject device	Same as predicate device #2

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
Energy$_{max}$ (J)	@1064 (PS): 0.73 @532 (PS): 0.3 @1064 (QS/OP): 1.2 @532 (QS/OP): 0.45 @694 (QS): 1.2	-	Same as the subject device	Same as predicate device #2
Fluence/dot$_{max}$ (J/cm^2)	@1064 (PS): 4.2 @532 (PS): 3.1 @1064 (QS/OP): 6 @532 (QS/OP): 3.5 @694 (QS): 3.7	-	Same as the subject device	Same as predicate device #2
Dot diameter (µm)	@1064 (PS): 550 @532 (PS): 450 @1064 (QS/OP): 550 @532 (QS/OP): 480 @694 (QS): 715	-	Same as the subject device	Same as predicate device #2
Coverage (%)	@1064 (PS): 27 @532 (PS): 15 @1064 (QS/OP): 26 @532 (QS/OP): 17 @694 (QS): 49.2	-	Same as the subject device	Same as predicate device #2
With microbeam handpiece (8 mm)				
Spot overall dimension (mm)	Round 8	-	Same as the subject device	Same as predicate device #2
Energy$_{max}$ (J)	@1064 (QS/OP): 0.95 @532 (QS/OP): 0.2 @694 (QS): 1.02	-	Same as the subject device	Same as predicate device #2
Fluence/dot$_{max}$ (J/cm^2)	@1064 (QS/OP): 38 @532 (QS/OP): 14 @694 (QS): 25	-	Same as the subject device	Same as predicate device #2
Dot diameter (µm)	@1064 (QS/OP): 210 @532 (QS/OP): 160 @694 (QS): 250	-	Same as the subject device	Same as predicate device #2
Coverage (%)	@1064 (QS/OP): 5 @532 (QS/OP): 2.5 @694 (QS): 8	-	Same as the subject device	Same as predicate device #2
Twain IPL				
Wavelengths (nm)	650-1200 625-1200 590-1200 570-1200	-	Same as the subject device	Same as predicate device #2

Specification	Subject device	Predicate device #1	Predicate device #2	Equivalence rationale
Device Name	*Discovery Pico*	*Enlighten III*	*Discovery Pico*	-
	550-1200 400-1200			
Pulse width$_{max}$	40 ms	-	Same as the subject device	Same as predicate device #2
Spot size (mm)	48 x 13 25 x 13	-	Same as the subject device	Same as predicate device #2
Fluence$_{max}$ (J/cm^2)	25	-	Same as the subject device	Same as predicate device #2
Repetition rate (Hz)	0.5	-	Same as the subject device	Same as predicate device #2

Discussion:

For this pre-market notification, no changes to the indications for use were made, although modifications were made to the Quanta K191842 device resulting in the proposed device. Upon comparison to the predicate devices, the proposed device's laser specifications are considered to be adequate for the safe and effective use of the device for its indications for use listed above.

4 Indication for 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 angioma
- 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, 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), 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.

5 Non-clinical tests

The present device was subject to non-clinical bench testing according to the following standards:

Table 4: Applied standards.

Standard	Discussion	e-star section
IEC 60601-1: 2005+AMD1: 2012 + AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1 tests have been repeated compared to test reports provided with K191842 due to standards edition update and some minor electrical components changes.	EMC, Wireless, & EMT Documentation
IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.	IEC 60601-1-2 tests have been repeated compared to test reports provided with K191842 due to standards edition update and some minor electrical components changes.	EMC, Wireless, & EMT Documentation
IEC 60601-1-6:2010/AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Usability engineering file (not provided with K191842) has been updated due to standards editions update.	-
IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices		-
IEC 62304:2006/AMD1:2015 Medical device software - Software life cycle processes	SW verification and validation activities have been repeated as SW and FW have been updated.	Software/Firmware & Cybersecurity/Interoperability
IEC 60601-2-22:2007+AMD1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22 tests have been repeated compared to test reports provided with K191842 due to standard edition update. Additionally, a test report to check pulse duration accuracy (according to IEC 60601-2-22: 2019) has been performed to verify technical change on pulse widths introduced with the present 510K. Pulse duration has been measured considering FWHM.	EMC, Wireless, & EMT Documentation
IEC 60825-1: 2014	Compared to test report provided with K191842,	EMC, Wireless, & EMT Documentation

Standard	Discussion	e-star section
Safety of laser products – Part 1: Equipment classification and requirements	IEC60825-1 report has been updated to include Rosso handpiece and some other formal updates.	
IEC 60601-2-57: 2011 Particular requirements for the basic safety and essential performance of non-laser light source equipment	No changes to Twain IPL affecting IEC60601-2-57 test reports.	-
ISO 10993-1: 2009 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	No changes affecting biocompatibility test reports except from the introduction of disinfection step during reprocessing for which a cytotoxicity test after reprocessing has been performed.	Reprocessing, Sterility, and Shelf-Life or Biocompatibility
ISO 17664-1: 2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices	Disinfection step has been introduced and thus reprocessing validation has been repeated.	Reprocessing, Sterility, and Shelf-Life

The results of the non-clinical performance standards testing support that the subject device can be used safely and effectively.

6 Clinical testing

N/A.

7 Conclusions

The proposed device uses the same applicable technology as that used in the predicate devices, and non-clinical performance testing was conducting with the criteria met. The differences in laser output specifications are considered to be adequate and do not raise new types of questions regarding safety and effectiveness for the indications for use. The proposed device is considered to be substantially equivalent to the predicate devices listed above.