November 18, 2020

Quanta System Spa
Francesco Dell'Antonio
Vice President Regulatory Affairs and QA
via Acquedotto, 109
Samarate (Va), 21017
Italy

Re: K202503
Trade/Device Name: Chrome
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: August 20, 2020
Received: August 31, 2020

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 and Part 809); 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202503

Device Name
Chrome

Indications for Use *(Describe)*

General intended use

Chrome 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)

Chrome 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 (pulsed)
Dermatology/Plastic Surgery:
Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis.
The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.
The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.
The laser is also indicated for the treatment of facial wrinkles.
Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as 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.
It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
The laser is also indicated for benign pigmented lesions to reduce lesion size, for patients with benign lesions that would potentiallybenefit from aggressive treatment, and for patients with benign lesions that have not responded to other laser treatments.
It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types.

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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5. 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:	10th November 2020
Device Name:	Chrome
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
Main Predicate Device	Pico Platform (K191842), Quanta System SpA
Reference Device	Evo family (K160368), Quanta System SpA

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

Description of the device:

Chrome is a laser family that includes Q-Switched and/or Pulsed laser sources, emitting at 532 nm and 1064 nm (Nd:YAG laser).
Chrome, 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.

Chrome, 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 or variable handpieces. The optical delivery system for the IPL system is a handpiece (Twain IPL) with fixed or interchangeable light filters at different wavelengths.

Chrome is controlled via a touch screen display housed in the front of the device.

Emission is triggered by means of a footswitch.

Indication for use
General intended use

Chrome 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)
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- 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 (pulsed)

Dermatology/Plastic Surgery:

Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis.
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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

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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.

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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.

Technological Characteristics Comparison

Specification	Main predicate device	Additional reference device	Subject device
Device Name (K number)	Pico Family K191842	EVO Platform K160368	Chrome
Submitter	Quanta System SpA	Quanta System SpA	Quanta System SpA
Product Code	GEX	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	II	II	II
Laser Sources	Nd:YAG, and Ruby	Nd:YAG, Ruby and Alexandrite	Nd:YAG
Laser Wavelengths [nm]	☒ 1064nm Q-Switched (Nanosecond mode) ☒ 1064nm (picosecond mode) ☐ 1064nm non-Q-Switched (pulsed mode) ☒ 532 nm Q-Switched (Nanosecond mode) ☒ 532 nm (picosecond mode) ☒ 694nm Q-Switched (Nanosecond mode) ☒ 694nm non-Q-Switched (free running mode)	☒ 1064nm Q-Switched (Nanosecond mode) ☒ 1064nm non-Q-Switched (pulsed mode) ☒ 532 nm Q-Switched (Nanosecond mode) ☒ 532nm pulsed ☒1320nm pulsed ☒ 755nm pulsed ☒ 694nm Q-Switched (Nanosecond mode) ☒ 694nm non-Q-Switched (free running mode)	☒ 1064nm Q-Switched (Nanosecond mode) ☒ 1064nm non-Q-Switched (pulsed mode) ☒ 532 nm Q-Switched (Nanosecond mode) ☐ 532nm pulsed ☐1320nm pulsed ☐ 755nm pulsed ☐ 694nm Q-Switched (Nanosecond mode) ☐ 694nm non-Q-Switched (free running mode) ☐ 532 nm (picosecond mode) ☐ 1064nm (picosecond mode)
IPL wavelengths [nm]	650-1200nm 625-1200nm 590-1200nm 570-1200nm 550-1200nm 400-1200nm	650-1200nm 625-1200nm 590-1200nm 570-1200nm 550-1200nm 400-1200nm	650-1200nm 625-1200nm 590-1200nm 570-1200nm 550-1200nm 400-1200nm
1064nm (Q-Switched, nanosecond mode)			
Homogeneous spot			
Pulse width	6 to 12 ns	6 to 12 ns	6 to 12 ns
Max Fluence	Up to 38J/cm^2	Up to 50J/cm^2	Up to 48J/cm^2
Spot Size	2 to 12 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 7x7 mm^2 Squared	2 to 12 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 9x9 mm^2 Squared	2 to 8 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 7x7 mm2 Squared

Specification	Main predicate device	Additional reference device	Subject device
Device Name (K number)	Pico Family K191842	EVO Platform K160368	Chrome
Submitter	Quanta System SpA	Quanta System SpA	Quanta System SpA
Repetition Rate	Up to 10 Hz	Up to 10 Hz	Up to 20 Hz
High coverage microbeam Handpiece	Present	Absent	Present
Microbeam handpiece Fluence per dot	6 J/cm^2	N/A	From 0.2 to 16.5 J/cm^2
Microbeam handpiece spot dimension (mm)	9 mm diameter	N/A	9 mm diameter
Standard microbeam Handpiece	Present	Absent	Present
Microbeam handpiece Fluence per dot	Up to 38J/cm^2	N/A	From 0.03 to 44.4 J/cm^2
Microbeam handpiece spot dimension (mm)	8 mm diameter	N/A	8 mm diameter
1064 nm (non Q-Switched – pulsed mode)			
Pulse width	N/A	0.25 to 300 ms	0.3 to 50 ms
Max Fluence	N/A	300 J/cm^2	300 J/cm^2
Spot Size	N/A	2 to 24 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 9x9 mm^2 Squared	2 to 8 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 7x7 mm2 Squared
Repetition Rate	N/A	Up to 10 Hz	Up to 10 Hz
532nm (Q-Switched, nanosecond mode)			
Homogeneous spot			
Pulse width	6 to 12 ns	6 to 12 ns	6 to 12 ns
Max Fluence	Up to 14 J/cm^2	Up to 19 J/cm^2	Up to 15 J/cm^2
Spot Size	2 to 12 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 7x7 mm^2 Squared	2, 4, 6, 8 mm diameter Round; 2x2, 3x3, 4x4, 5x5 mm2 Squared	3 to 10.5 mm diameter Round; 2x2, 3x3, 4x4, 5x5, 7x7 mm2 Squared
Repetition Rate	Up to 10 Hz	Up to 10 Hz	Up to 20 Hz
High coverage microbeam Handpiece	Present	Absent	Present
Microbeam handpiece Fluence per dot	3.5 J/cm^2	N/A	from 0.05 to 5.95 J/cm2

Specification	Main predicate device	Additional reference device	Subject device
Device Name (K number)	Pico Family K191842	EVO Platform K160368	Chrome
Submitter	Quanta System SpA	Quanta System SpA	Quanta System SpA
Microbeam handpiece spot dimension (mm)	9 mm diameter	N/A	9 mm diameter
Standard microbeam Handpiece	Present	Absent	Present
Microbeam handpiece Fluence per dot	Up to 14 J/cm^2	N/A	From 0.3 to 14.9 J/cm2
Microbeam handpiece spot dimension (mm)	8 mm diameter	N/A	8 mm diameter
IPL 650-1200 nm, 625-1200 nm, 590-1200 nm, 570-1200 nm, 550-1200 nm, 400-1200 nm			
Pulse width	Up to 40ms	Up to 40ms	Up to 40ms
Max Fluence	up to 25 J/cm^2	up to 25 J/cm^2	up to 25 J/cm^2
Spot Size	48mm x13 mm 25mm x13 mm	48mm x13 mm 25mm x13 mm	48mm x13 mm 25mm x13 mm
Repetition Rate	up to 0,5 Hz	up to 0,5 Hz	up to 3 Hz

Performance data:

The subject device was subjected to performance testing in accordance with the following recognized consensus standards:

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

- IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

- IEC 60601-2-22: 2012-10 ed 3.1, 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 Ed. 3.0 (2014) Safety of laser products – Part 1: Equipment classification and requirements

The following testing were performed on the subject device:

- 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:

Biocompatibility of the subject device was established based on a comparison to the legally-marketed predicate device, as the patient-contacting components of the subject device in its final finished form are identical to that of K191842 in formulation, processing, sterilization, and geometry, and no other chemicals have been added.

Conclusions:

The subject device has the same intended use, the same indications for use and the same fundamental scientific technology as its predicates.

The performance specification of the subject device are equivalent to its identified predicate devices and therefore do not present any new concerns of safety and effectiveness.

Therefore, Chrome is as safe, as effective, and performs as well as the legally marketed predicate devices.