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

April 5, 2016

Quanta System SPA
Mr. Francesco Dell'Antonio
Head of Regulatory Affairs
Via IV Novembre, 116
21058 - Solbiate Olona (VA) - Italy

Re: K160368
Trade/Device Name: EVO Platform
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: March 15, 2016
Received: March 17, 2016

Dear Mr. 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); 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" (21CFR 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 yours,

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)*
K160368

Device Name
EVO Platform

Indications for Use *(Describe)*
The EVO Platform 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 EVO Platform 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.

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 pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with 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.

532 nm (pulsed)

Intended for the coagulation and hemostasis of vascular lesions.

Dermatology/Plastic Surgery:
For photocoagulation and hemostasis of vascular and cutaneous lesions in dermatology including but not limited to the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or ex-tremities telangiectasias, venous anomalies, leg veins]; benign pigmented lesions (nevi, lentigines, chloasma, cafe au- lait, tattoos (red and green ink), verrucae, skin tags, keratoses, plaques, cutaneous lesion treatment (hemostasis, color lightening,

blanching, flattening, reduction of lesion size).

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.

755 nm (pulsed)

Indicated 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 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1320 nm (pulsed)
Indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and haemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles, fine lines and wrinkles, and the treatment of back acne and atrophic acne scars.

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 EVO Platform 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 fluences for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.

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.

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5. SPECIAL 510(K) SUMMARY – DEVICE MODIFICATIONS

Introduction:

This document contains the 510(k) Summary for the EVO Platform.
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 IV Novembre, 116 Solbiate Olona (VA) Italy, 21058
510(k) Contact Person:	Francesco Dell'Antonio Head of Regulatory Affairs Quanta System SPA Email: francesco.dellantonio@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815
Date Prepared:	February 5th, 2016
Device Name:	EVO Platform
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 (K152012), Quanta System SpA NaturaLase PiQo4 Laser (K151473) , FOCUS MEDICAL, LLC. PicoWay Laser System (K142372, K150326) Candela Corporation

The modified device EVO Platform is claimed to be derived from the legally marketed (unmodified) device EVO Platform (K152012).

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, as follows.

The EVO Platform 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, 1320 nm (Nd:YAG laser), 694 nm (Ruby laser), or 755 nm (Alexandrite laser).
The EVO Platform 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 EVO Platform 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 for Q-switched sources and an optical fiber with focusing handpieces for pulsed sources. 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 EVO platform 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 EVO Platform 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 EVO Platform 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 EVO Platform 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-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.

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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.

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 pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with 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.

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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.

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1320 nm (pulsed)

Indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and haemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles, fine lines and wrinkles, and the treatment of back acne and atrophic acne scars.

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

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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.

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Indicated for inflammatory acne (acne vulgaris).

Integrated Skin Cooler

The intended use of the integrated cooling system in the EVO Platform 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 fluences for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.

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 60601-1:2005, Mod - 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 EVO Platform is established based on the predicate devices.

Substantial Equivalence:

The modified EVO Platform has the same intended use, the same indications for use and the same fundamental scientific technology as the unmodified EVO Platform (K152012).

The performance specification of modified EVO Platform are the same as the unmodified EVO Platform (K152012), except for some laser parameters, which fall under the range used by the identified predicate devices and therefore do not present any new concerns of safety and effectiveness.

Therefore, the EVO Platform is substantially equivalent to its predicate devices.