



Food and Drug Administration
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December 21, 2015

Quanta System SPA
Francesco Dell'antonio
Head of Regulatory Affairs Department
Via IV Novembre, 116
Solbiate Olona (VA), 21058 IT

Re: K152714

Trade/Device Name: Quanta Forte
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: II
Product Code: GEX, ONF
Dated: November 23, 2015
Received: December 3, 2015

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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar -S

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

Indications for Use

510(k) Number (if known)
K152714

Device Name
Quanta Forte

Indications for Use (Describe)

Quanta Forte and its Hand Pieces are intended for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical specialties of dermatology and general and plastic surgery.

Quanta Forte with 808nm Laser Handpiece is indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.

Quanta Forte with 415-950nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale.

Quanta Forte with 535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick Scale.

Quanta Forte with 580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Hair removal and Permanent Hair Reduction* in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 2940 nm Er-Yag Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to:
Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

Quanta Forte with 1064 nm Long Pulse (LP) Nd:YAG Laser Handpiece is indicated for:

- Removal of unwanted hair, for stable long-term, or permanent, hair reduction* through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PEB)

* 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.

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*)

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5. 510(K) SUMMARY

Introduction:

This document contains the 510(k) Summary for the Quanta Forte device.
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
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Italy, 21058

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Date Prepared: 14/09/2015

Device Name: Quanta Forte

Classification: Class II

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.

Regulation Number: 21 CFR 878.4810

Predicate Devices:

Quanta Forte is substantially equivalent to the following legally marketed predicate devices:

- K143519 Medistar Next Family - Asclepion Laser Technologies GmbH
- K111303 Omnimax - Sharplight Technologies Ltd

Description of the device:

Quanta Forte system is an Intense Pulsed Light (IPL) and laser emitting device that is operated with a handpiece in contact with the skin.

Quanta Forte comprises a main console unit and several handpieces that are triggered by means of a footswitch or a finger switch.

A microprocessor based system controller is used to monitor and direct all the system functions and the graphic user interface.

The main console can be connected to the following handpieces:

- 415-950 nm Intense Pulsed Light
- 535-950 nm Intense Pulsed Light
- 580-950 nm Intense Pulsed Light
- 635-950 nm Intense Pulsed Light
- 808 nm laser diode
- 1064 nm ND:YAG laser
- 2940 nm Erbium:YAG laser

Intended use

Quanta Forte and its Hand Pieces are intended for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical specialties of dermatology and general and plastic surgery.

Quanta Forte with 808nm Laser Handpiece is indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.

Quanta Forte with 415-950nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale.

Quanta Forte with 535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick Scale.

Quanta Forte with 580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Hair removal and Permanent Hair Reduction* in all skin types (I-VI) to the Fitzpatrick scale.

Quanta Forte with 2940 nm Er-Yag Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to:
Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

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Removal or lightening of unwanted hair (with and without adjuvant preparation)
Treatment of pseudofolliculitis barbae (PEB)

* 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.

Comparison of Technological Characteristics:

Quanta Forte has the same technological characteristics (energy source, laser/IPL source, control mechanism) and specifications as its predicate devices.

Performance data:

The following performance data are provided in support of the substantial equivalence determination:

Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Quanta Forte device.

The system complies with the IEC 60601-1, IEC 60601-2-22, IEC 60601-2-57 standards for safety and the IEC 60601-1-2 standard for EMC.

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".

Comparison of Intended Use:

Quanta Forte device's Intended Use combines the Intended Uses of its predicate devices.

Substantial Equivalence:

The Quanta Forte device is as safe and effective as its predicate devices.

The Quanta Forte device has the same intended use and same technological characteristics and specifications as its predicate devices.

Thus, Quanta Forte device is substantially equivalent to its predicate devices.