K 083207

510(k) SUMMARY

Title: **Quanta System Ultrawave III EX 1320**

NOV 1 4 2008

Submitter: Quanta System SpA
via IV Novembre,116
21058 Solbiate
Olona VA / Italy

Contact: Dr. Isabella Carrer
Medical Division Manager

Date Prepared: July 11, 2008

Device Trade Name: Quanta System Ultrawave III EX 1320

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

Classification Name: Instrument, surgical, powered, laser

Predicate Devices:

- Quanta System S.p.A ULTRAWAVE II EX 1320 **(K070805)**
- Adept Medical Concept 1064/532/755 Laser **(K032218)**

Intended Use / Indications for Use:

Device Name: **Ultrawave III EX 1320**

Nd:YAG 1064nm

Intended for general surgical applications; dermatology/plastic surgery; endoscopic/laparoscopic surgery; general surgery; gynecology; ENT; hemostasis; neurosurgery; oculoplastics; pulmonary surgery; thoracic surgery; urology; and orthopedics.

General Surgical Applications:
Incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology/plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/-otorhinolaryngology (ENT),

neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery and urology.

Dermatology/Plastic Surgery:
Coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins and poikiloderma of Civatte and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis . It addition, the laser is 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, keratoses, tattoos (significant reduction in the intensity of blue and/or black tattoos), and plaques.

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.

The laser is also indicated for the treatment of facial wrinkles.

It is indicated for the removal of unwanted hair, for the stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).

It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

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.

Orthopedics:

Cutting, ablation, and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Pulmonary Surgery:

Palliative treatment of benign and malignant

pulmonary airway obtructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery:

Incision, excision, coagulating and vaporization of soft tissue. Thoracic applications, including but not limited to, isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets; vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (thoracoscopy).

Urology:

All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures and lesions of the external genitalia (including condyloma acuminate).

Nd:YAG 1320nm

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.

Nd:YAG 532nm

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-tremitics 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.

General Surgery:

Vaporizing, Coagulating, Incising , Excising, Debulking, and Ablating of Soft Tissue as well as in Endoscopic (e.g., laparoscopic) or open surgeries.

Gastroenterology:

Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric Erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Head and NecMOtorhinolaryngology (ENT):

Tissue incision, excision, ablation, and vessel hemostasis

Hemostasis during Surgery:

Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g., laparoscopic) and open surgery.

Neurosurgery:

Hemostasis for: Pituitary Tumor, Meningioma; hemagioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

Ophthalmology:

Post-vitrectomy endophotocoagulation of the retina.

Pulmonary Surgery:

Palliative treatment of benign and malignant pulmonary airway obstructions, including Squamous Cell Carcinoma, Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

Thoracic Surgery:

Cutting (incision and excision), coagulating, and vaporizing of soft tissue Thoracic applications including, but not limited to: Isolation of vessels for endartecetomy and/or by-pass grafts, Wedge Resections, Thoractoniy, Formation of Pacemaker pockets. Vaporization, coagulation, incision and excision, debulking, and ablation oflung tissue (Thoracoscopy)

Urology:

All applications including: Superficial urinary bladder tumors, invasive bladder carcinoma; Urethral Strictures; Lesions of the external genitalia (including condyloma acuminata).

***Alexandrite* 755nm**

Intended for coagulation and hemostatis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I-VI, including suntanned skin types. Also indicated for pigmented lesions and wrinkles.

IPL

590-1200nm ; 625-1200nm; 650-1200nm

Indicated for permanent hair reduction.

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.

400-1200nm

Indicated for inflammatory acne (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 vascular lesion, and to reduce the potential side effects of laser treatments. Any other different use is considered incorrect.
Technological Characteristics:	The Ultrawave III EX 1320 consists of two laser sources and an IPL. The laser sources emit wavelengths of 1064nm (long pulse and short pulse),1320nm and 532nm for the Nd:YAG source and 755nm for the Alexandrite source. The IPL has several different spectral ranges to be utilized for different applications: 400-1200nm, 550-1200nm, 570-1200nm, 590-1200nm, 625-1200nm and 650-1200nm. In addition, the Ultrawave III EX 1320 includes a power supply; a cooling system; an optical delivery system; a microprocessor based controller; an integral skin cooler; and safety features to ensure use of the appropriate laser, wavelength and hand piece.
Performance Data	Performance data was provided showing the Ultrawave III EX 1320 is capable of performing fractional photothermolysis, i.e., creation of pattern (lattice) of microscopic islets of damage at superficial skin layers.
Substantial Equivalence:	The Quanta System Ultrawave III EX 1320 is as safe and effective as the predicate devices. The Ultrawave III EX 1320 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Ultrawave III EX 1320 and its predicate devices raise no new issues of safety or effectiveness. Thus, the Ultrawave III EX 1320 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2008

Quanta System S.P.A.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street Northwest
Buffalo, Minnesota 55313

Re: K083207
Trade/Device Name: Ultrawave III EX 1320
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
Dated: October 30, 2008
Received: October 31, 2008

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 083207

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Neil R. Ogden for M.A.C.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083207

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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Dermatology/Plastic Surgery:

Neil R. Ogden for MM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083207

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Ophthalmology:

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Pulmonary Surgery:

Neil R S Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083207

Palliative treatment of benign and malignant pulmonary airway obstructions, including Squamous Cell Carcinoma, Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

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Indicated for inflammatory acne (acne vulgaris).

Integrated Skin Cooler

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083207

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 vascular lesion, and to reduce the potential side effects of laser treatments.
Any other different use is considered incorrect.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083207