K073549

510(k) SUMMARY

Title:	Quanta System Q-Plus T
Submitter:	Quanta System SpA via IV Novembre,116 21058 Solbiate Olona VA / Italy
Contact:	Dr. Isabella Carrer Medical Division Manager
Date Prepared:	June 28, 2007
Device Trade Name:	Quanta System Q-Plus T
Common Name:	Laser surgical instrument for use in general surgery and dermatology
Classification Name:	Instrument, surgical, powered, laser
Predicate Devices:	- Cynosure, Inc Affinity QS Q-Switched Nd:YAG Laser System (K050382); - ASCLEPION LASER TECHNOLOGIES GmbH TattooStar R (K060787)

Intended Use / Indications for Use:

Nd:YAG (1064nm) and (532nm)

The Q-Plus T Q-Switched laser 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.

Ruby (694nm)

The Q-Plus T Q-Switched laser is intended for use for cutting, vaporization and ablation of soft tissue and the removal of tattoos and benign pigment lesion.

Some examples of pigment lesions are

- Lentigines
- café-au-lait-blotches

- Ephalides
- Benign Naevi such as:
    - Naevus of Ota
    - Naevus of Ito
    - Epidermal Naevi
    - Congenital Naevi
    - Beckers Naevi
    - Blue Nevus
    - Naevus Spillus
    - Mongolian Spot

Technological Characteristics:	The device includes a Q-Switched Nd:YAG laser source with 1000mJ max energy at 1064 nm and 500mJ max energy at 532 nm wavelengths, and a Q-Switched Ruby laser source with 1000mJ max energy at 694nm wavelength. The optical delivery system for the three wavelengths is the articulated arm. In addition, the Q-Plus T includes a power supply; a cooling system; an optical delivery system; a microprocessor based controller; and safety features to ensure use of the appropriate laser, wavelength and hand piece.
Performance Data	None
Substantial Equivalence:	The Quanta System Q-Plus-T is as safe and effective as the predicate devices. The Q-Plus T has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Q-Plus T and its predicate devices raise no new issues of safety or effectiveness. Thus, the Q-Plus T is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

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

Re: K073549
Trade/Device Name: Q-Plus T
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: February 18, 2008
Received: February 19, 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):_____

Device Name: Q-Plus T

Indications for Use:

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  - Naevus Spillus
  - Mongolian Spot

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

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

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

_____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

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