

K073549

Title: 510(k) SUMMARY  
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.



FEB 28 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Quanta System, S.P.A.  
% Regulatory Technology Services, LLC  
Mr. Mark Job  
1394 25<sup>th</sup> 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

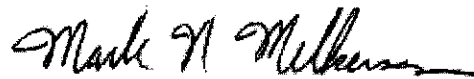
Page 2 – Mr. Mark Job

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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  - Beckers Naevi
  - Blue Nevus
  - Naevus Spillus
  - Mongolian Spot


Prescription Use   X    
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use         
(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)

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

510(k) Number K 073549