

K103539

**Title:** 510(k) SUMMARY  
Quanta System DUOLITE

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

**Contact:** Dr. Maurizio Bianchi  
QA and Regulatory Affairs Manager

**Date Prepared:** February 28, 2013

**Device Trade Name:** Quanta System DUOLITE

**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);

**Intended Use / Indications for use:** Nd:YAG (1064nm):  
The DUOLITE Q-Switched laser is intended for treatment of vascular lesions, pigmented lesions, and for hair removal and the incision, excision, ablation, vaporization of soft tissue for general dermatology. The DUOLITE Q-Switched laser is intended for tattoo removal ( blue, black and green tattoo)

Nd:YAG (532nm):  
The DUOLITE Q-Switched laser is intended for treatment of vascular lesions, pigmented lesions, and for hair removal and the incision, excision, ablation, vaporization of soft tissue for general dermatology. The DUOLITE Q-Switched laser is intended for tattoo removal (red, violet, orange, yellow and brown tattoo)

**Technological Characteristics:** The device includes a Q-Switched Nd:YAG laser source with 900mJ max energy at 1064 nm and 450mJ max energy at 532 nm wavelengths. The optical delivery system for the two wavelengths is the articulated arm.  
In addition, the DUOLITE 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 DUOLITE is as safe and effective as the predicate devices. The DUOLITE has the same intended uses and similar indications, technological characteristics,

and principles of operation as its predicate device as demonstrated in the table below.

|   | Wavelength<br>[nm] | pulse<br>width<br>[ns] | Fluence<br>[J/cm <sup>2</sup> ]   | spot<br>size<br>(mm) | Rep.<br>rate<br>[Hz] |
|---|--------------------|------------------------|---|----------------------|----------------------|
| <b>QUANTA<br/>SYSTEM<br/>DUOLITE</b>          | 1064 nm            | 6 ns                   | 28J/cm <sup>2</sup> at 2mm<br>12J/cm <sup>2</sup> at 3mm<br>3J/cm <sup>2</sup> at 6mm                               | 2,3 and<br>6mm       | 1,2,5<br>and<br>10Hz |
|   | 532 nm             | 6 ns                   | 14J/cm <sup>2</sup> at 2mm<br>6J/cm <sup>2</sup> at 3mm<br>1,5J/cm <sup>2</sup> at 6mm                              | 2,3 and<br>6mm       | 1,2,5<br>and<br>10Hz |
| <b>CYNOSURE<br/>AFFINITY<br/>QS (K050382)</b> | 1064 nm            | 6 ns                   | 28J/cm <sup>2</sup> at 2mm<br>12J/cm <sup>2</sup> at 3mm<br>7J/cm <sup>2</sup> at 4mm<br>3J/cm <sup>2</sup> at 6mm  | 2,3,4<br>and<br>6mm  | 1,2,5<br>and<br>10Hz |
|   | 532 nm             | 6 ns                   | 14J/cm <sup>2</sup> at 2mm<br>6J/cm <sup>2</sup> at 3mm<br>3J/cm <sup>2</sup> at 4mm<br>1,5J/cm <sup>2</sup> at 6mm | 2,3,4<br>and<br>6mm  | 1,2,5<br>and<br>10Hz |

The tip of the handpiece of the DUOLITE is made of Biocompatible material as the predicate device. This Sterilization method is the same as its predicate device. The Minor technological differences between the DUOLITE and its predicate devices raise no new issue of safety or effectiveness. Thus, the DUOLITE is substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

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

March 15, 2013

Re: K103539  
Trade/Device Name: DUOLITE  
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: January 06, 2011  
Received: January 07, 2011

Dear Mr. Job:

This Letter corrects our substantially equivalent letter of January 20, 2011.

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 (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 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,  
FOR

**Peter D. Rumm -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known):     K103539    

Device Name: **DUOLITE**

**Indications for use:**

**Nd:YAG (1064nm):**

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Neil R Ogden  
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(Division Sign Off) for MXM  
Division of Surgical, Orthopedic,  
And Restorative Devices

510(k) Number     K103539    

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

Over-The-Counter Use       
(21 C.F.R. 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)