AUG 2 5 2011

K111592

510(k) SUMMARY

Title: **Quanta System YOULASER CO2**

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

Contact:
Maurizio Bianchi
Regulatory Affairs Manager

Date Prepared: July 19th, 2011

Device Trade Name: Quanta System YOULASER CO2

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

Classification Name: Instrument, surgical, powered, laser

Predicate Devices:
- **El.En S.p.A Smart CO2 Laser System (K072159);**

Intended Use / Indications for Use: YOULASER CO2 Laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery.
YOULASER CO2 Laser with the scanning unit is indicated for full ablative skin resurfacing for the following application:
Dyschromia,
Atrophic + Acne scars,
Hypertrophic scars

The scanning modality is intended for the above described use. In this case the handpiece simply enables a laser-tissue interaction in different positions within a specific area.

The safety and effectiveness of this scanner/device has not been evaluated as a fractionated scanner/device

Technological Characteristics:

The YOULASER CO2 Laser System includes 1 model :

Models	Wavelength	Laser Power
YOULASER CO2	10.6μm	30W

The YOULASER CO2 Laser is composed externally of a metallic shell with a frontal polyurethane panel containing the touch screen display. On this panel the key switch, emergency red push button and the operation led are inserted too. On the rear panel the footswitch connector, the remote interlock, the power switch are located.
The laser system is composed of power supply, CO_2 laser source with air cooling system, optical bench, articulated arm with CO_2 scanner, the control electronics.
The electronic, based on a microcontroller, manages the voltage power supply and the CO_2 laser source.

Performance Data

None

Substantial Equivalence:

The Quanta System YOULASER CO2 is as safe and effective as the predicate devices. The YOULASER CO2 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the YOULASER CO2 and its predicate devices raise no new issues of safety or effectiveness. Thus, the YOULASER CO2 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

AUG 25 2011

Re: K111592
Trade/Device Name: Youlaser CO_2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 11, 2011
Received: August 12, 2011

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. 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.

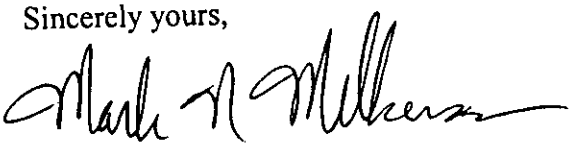
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K111592

Device Name: **YOULASER CO2**

Indications for Use:

YOULASER CO2 Laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery.
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Mark RP Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111592

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)