510(K) Summary

K062762

Submitter:	El.En. S.p.A. via Baldanzese, 17 50041 Calenzano (FI), Italy
Contact:	Andrea Tozzi Quality System Manager & Official Correspondent
Date Summary Prepared:	September 5, 2006

MAR 0 1 2007

Device Trade Name:	Derma YAG
Common Name:	Dermatology Laser
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Smartepil Laser
Device Description:	The Derma YAG Laser is a pulse Nd:YAG laser utilizing the Nd:YAG crystal as the lasing medium. It is a pulsed laser with a wavelength of 1064nm. Laser activation is by a footswitch. Overall weight of the laser is 63 kg, and the size is 80 cm x 42 cm x 80 cm (H x W x D). Electrical requirement is 220VAC, 12A, 50-60 Hz, single phase.
Intended Use:	The Derma YAG Laser is indicated for benign vascular lesions and hair removal.
Comparison:	The Derma YAG Laser is substantially equivalent to the Cynosure Smartepil Laser. They are both pulse Nd:YAG lasers for the identical indications for use.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Derma YAG Laser is another safe and effective device for dermatological vascular lesions and hair removal.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

El.En.S.p.A.
% Ms. Andrea Tozzi
Quality System Manager
and Official Correspondent
Via Baldanzese, 17
50041 Calenzano (FI), Italy

MAR 0 1 2007

Re: K062762
Trade/Device Name: Derma YAG
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: January 10, 2007
Received: January 12, 2007

Dear Ms. Tozzi:

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 Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

510(K) Number (if known): K062762

Device Name: Derma YAG

Indications For Use:

The Derma YAG Laser is indicated for benign vascular lesions and hair removal.

Prescriptive Use _____ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE NO 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 K062762

(Optional Format 1-2-96)