

SEP 26 2005

510(K) Summary

K051537
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Submitter: El En
Via Baldanzese, 17-50041
Calenzano (Florence), Italy

Contact: Andrea Tozzi
Director, Quality Assurance

Date Summary Prepared: June 9, 2005

Device Trade Name: HILT Family Laser

Common Name: Nd:YAG laser

Classification Name: Infrared Lamp
21 CFR 890.5500

Equivalent Device: MLT-1000 IR Laser System

Device Description: The HILT Family Laser provides 1,064 nm wavelength. Laser emission activation is by used selectable controller. Electrical requirement is 230 VAC, 15A, 50-60 Hz, single phase.

Intended Use: The HILT Family Laser is intended to provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Comparison: The HILT Family Laser has the same indications for use, the same principle of operation, and similar performance specifications as the predicate devices.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The HILT Family Laser is a safe and effective device for the indications specified.

Additional Information: none

Name of Manufacturer: El En SpA (Italy), represented by Cynosure, Inc.

Laser Model Name and Number: HILT Family Laser: HILT I, HILT II, HILT III; Nd:YAG laser, Infrared Lamp System.

Laser Type: (Circle all that apply)
Alexandrite, Argon, CO₂, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other _____

Indications in this application: To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle & joint pain & stiffness, arthritis pain or muscle spasm; the temporary increase in local blood circulation &/or promoting relaxation of muscle.

FDA Document Control Number: K051537/S001

FDA Product Code: 90 ILY

Reviewer Computer Initials: ABC

Date of Clearance Letter: 9/16/05

Basis of Approval: (Circle all that apply)
Predicate Device (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser: The Hilt Family Laser: HILT I, HILT II, HILT III is a Nd:YAG laser, Infrared Lamp system for heat therapy. The three possible treatment configurations are Hilt I, contact; Hilt II, non-contact; Hilt III, both contact and non-contact. The non-contact hand piece utilizes a spacer between the output window and the skin of the patient.

Operation Modes: (Circle all that apply)
CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other _____

Wavelength in Nanometers: 1064 nm

Power/Energy Range (Watts): 10 Maximum

Pulse Width: Hilt I, 60-150 μ s; Hilt II, 80-120 μ s; Hilt III, 60-100 μ s

Repetition Rate: Hilt I, 10-30 Hz; Hilt II, 10-40 Hz; Hilt III, 10-30 Hz

Delivery System: Contact and Non-contact hand pieces connected to the system via a 600 μ m diameter fiber optic cable.

Comments:



SEP 26 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Cho
Sr. Vice President
Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K051537

Trade/Device Name: El En HILT Family Laser (HILT I, HILT II, HILT III)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 19, 2005
Received: August 22, 2005

Dear Mr. Cho:

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.

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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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051537

Device Name: El En HILT Family Laser (HILT I, HILT II, HILT III)

Indications For Use:

The HILT Family Laser is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler MD for MKM
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K051537