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510(k) Summary

NOV - 7 2008

Submitted by:

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Contact Person:

Lewis Ward
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USA

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Date Prepared: 10-27-08

Device Trade Name: Infrared Lamp

Classification Name: Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulation Class: II
Product Code: ILY

Intended Use: Intended for the relaxation of muscles and relief of muscle spasms; temporary relief of minor muscle and joint aches, pains, and stiffness; temporary relief of minor pain and stiffness associated with arthritis; and to temporarily increase local blood circulation.

Technological Characteristics: The DPL™ Therapy System is a compact infrared lamp for therapeutic heating. It delivers infrared light to the skin resulting in a safe elevation of the skin temperature for therapeutic effects. The device is comparable in design, technology, and output to the Dermillume HR 1000 infrared lamp product. The lamps are contained in two panels on a desk stand. The panels are detachable for use individually or as a pair on the body. The product has an automatic 17-minute timed cycle which may be repeated by activating the ON cycle. Device takes 8 minutes to reach target temperature on skin. Total time for treatment is 17 minutes.

Substantial Equivalence: The DPL™ Therapy System is substantially equivalent to the Dermillume Red HR 1000 device, 510(k) K051681. The DPL™ Therapy System furnishes therapeutic heating comparable to the predicate.

Test Data: The device conforms to the electrical safety requirements established in IEC 60601-1-1:2000 and complies to the electromagnetic compatibility requirements in EN 60601-1-2:2001. Clinical studies demonstrate that therapeutic heat is attained for male and female subjects. Safe temperatures were maintained for the duration of the treatment time. No adverse effects at complications were encountered. The DPL System's device is safe, as effective, and performs comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LED Technologies, LLC
% L.W. Ward Associates, Inc.
Mr. Lewis Ward
4655 Kirkwood Court
Boulder, Colorado 80301

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Re: K081570
Trade/Device Name: DPL™ Therapy System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: October 29, 2008
Received: November 3, 2008

Dear Mr. Ward:

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 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

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

Enclosure

K081570

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: DPL™ Therapy System

Indications for Use:

Intended for the relaxation of muscles and relief of muscle spasms; temporary relief of minor muscle and joint aches, pains, and stiffness; temporary relief of minor pain and stiffness associated with arthritis; and to temporarily increase local blood circulation.

Prescription Use _____ AND/OR Over-the-Counter Use __X__
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K081570