K 083560

510(k) Summary
(per 21 CFR 807.92(c))

1. Applicant

Lighthouse Technical Innovations, Inc.
701 Northlake Blvd., Suite 101
North Palm Beach, FL 33408

DEC 11 2008

Contact Person: Eugene Barnett, Vice President
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Date Prepared: July 1, 2008

2. Device Name

Trade Name: Expanded Spectrum Photo Therapy Device (ESPT-3X)
Common/ Usual Name: Infrared Lamp
Classification Name: Lamp, Infrared, Therapeutic Heating
Regulation Number: 890.5500
Product Code: ILY
Classification: II
Panel: Physical Medicine

3. Predicate Devices

The ESPT-3X is equivalent to the following devices:

Device	510(k) Number	Manufacturer
Alt Laser, Model VTR 75	K031612	Avicenna Laser Technology, Inc.
K-Laser 6d-zh	K050070	Eltech, S.R.L.
K-Laser Desktop 6d	K050070	Eltech, S.R.L.

4. Intended Use

The Expanded Spectrum Photo Therapy Device (ESPT-3X) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for:

- the temporary relief of minor muscle and joint pain and stiffness,
- minor arthritis pain,
- muscle spasm,

- the temporary increase in local blood circulation and/or
- promoting relaxation of muscle.

The ESPT-3X is for prescription use only.

5. Description of the Device

The ESPT-3X console is a non-invasive, portable, therapeutic medical laser designed to deliver high level (Class IV) energy/power for the purpose of reducing musculoskeletal pain. A "hand piece" accessory evenly delivers a Class IV laser to the target tissue. This channel is equipped with a red aiming beam (1 mW) that provides visible illumination of the area being treated. The console is equipped with a separate and independent timer that is manually set by the operator.

6. Technical Characteristics and Substantial Equivalence

The ESPT-3X provides Class IV therapy for reducing musculoskeletal pain and has the same technological characteristics (e.g., wavelength, power, and frequency) as other commercially available Class IV devices. In addition, the ESPT-3X was tested extensively to ensure conformance to applicable standards and FDA regulations. In summary, the ESPT-3X is substantially equivalent to the predicate devices listed in this 510(k) submission such that they share the same Indications for Use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lighthouse Technical Innovations, Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 E. Aurora Road, Unit B7
Twinsburg, Ohio 44087

DEC 11 2008

Re: K083560
Trade/Device Name: The Expanded Spectrum Photo Therapy Device (ESPT-3X)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 1, 2008
Received: December 2, 2008

Dear Mr. Lehtonen:

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

Enclosure

Indications for Use

510(k) Number (if known): K 083560

Device Name: The Expanded Spectrum Photo Therapy Device (ESPT-3X)

Indications for Use:

The Expanded Spectrum Photo Therapy Device (ESPT-3X) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for:

- the temporary relief of minor muscle and joint pain and stiffness,
- minor arthritis pain,
- muscle spasm,
- the temporary increase in local blood circulation and/or
- promoting relaxation of muscle.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

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

510(k) Number K083560