K061080

JUN 14 2006

F. 510(k) Summary

Submitters information: Lhasa OMS, Inc.
230 Libbey Parkway
Weymouth, MA 02189

Establishment Registration: 1222811

Contact Person: Mark W. Sheehan

Telephone: 781-340-1072 ext. 20
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Date Summary Prepared: April 14, 2006

Device name:
Proprietary name: IR Pro 250
Common or usual name: Infrared Heating Lamp
Classification name: Lamp, Infrared, Class II, 21 CFR 890.5500

Legally marketed device for substantial equivalence comparison:
TDP CQ-27 Lamp, K003538

Description of the device:
The IR Pro 250 lamp can be used for topical heating of the body. It is designed to emit light between 700 to 50,000 nanometers in wavelength. The lamp uses 120 volts AC power at 250 watts. It is mounted on a swivel stand with 5 casters. An automatic timer controls exposure time.

Intended use of the device:
The IR Pro 250 is intended for use in the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may help muscle spasms, minor sprains and strains, and minor back pain. The intended use of the TDP CQ-27 Lamp is identical.

Application should be pleasant and comfortable. If pain or discomfort is experienced treatment should be discontinued. Misuse may cause burns.

Technological Characteristics:
The IR Pro 250 and the TDP uses 120 volts, AC 60 Hz power. Each device emits infrared heat. The IR Pro 250 uses a 250 watt infrared bulb and the TDP lamp uses an emission plate to generate heat.

Standards: A sample of the device was tested in accordance with the Standard for Safety for Portable Sun/Heat Lamp, UL-482, 9th Edition, September 2, 2005: UL 482/21, UL 482/22, UL 482/24, UL 482/26, UL 482/27, UL 482/29

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Lhasa OMS, Inc.
% Mr. Mark W. Sheehan
Regulatory Affairs Officer
230 Libbey Parkway
Weymouth, Massachusetts 021089

Re: K061080
Trade/Device Name: IR Pro 250
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 5, 2006
Received: June 6, 2006

Dear Mr. Sheehan:

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) 276-0120. 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

G. Indications for Use

510(k) Number (if known): Device Name: IR Pro 250

Intended use of the device:
The IR Pro 250 is intended for use in the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may help muscle spasms, minor sprains and strains, and minor back pain.

Prescription Use _____ AND/OR Over-The-Counter Use____X_____(Part 21 CFR 810 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)

Barbara Bucinski

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

510(k) Number K061080