JUN - 4 2001

K003538

LHASA MEDICAL, INC.

234 Libbey Parkway, Weymouth, MA 02189 (781) 340-1071 fax: 781-659-9916
(or fax: 781-335-6296)

March 5, 2001

 (revised from 11/15/00 and 1/22/01)

PRE-MARKET NOTIFICATION 510(k) SUMMARY
(As Required by 21 CFR 807.92)

(a)(1)

Submitter:	Lhasa Medical, Inc 234 Libbey Parkway Weymouth, MA 02189 phone: (781) 340-1071
Contact Person:	Mrs. Kyung P. Riihimaki
Date Summary Prepared:	March 5, 2001 (revised from 11/15/01 and 1/22/01)

(a)(2)

Name of Device:	TDP CQ-27 Heat Lamp
Common or Usual Name:	Infrared Heating Lamp
Product Code:	ILY
Classification:	Class II
510(k) Number:	K-003538

..... continued on next 2 pages (Page 6b and Page 6c)

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PRE-MARKET NOTIFICATION 510(k) SUMMARY ..... continued from previous page

(a)(3)
The TDP CQ 27 Heat Lamp is substantially equivalent in design and performance to other brands of infrared heating lamps which have been found to be substantially equivalent through the 510(k) premarket notification process. These include the following:

- Firard II TDP Lamp, Helio Medical Supplies, 510k #: K-960036
- TDP Infrared Heat Lamp, Toxicology Professionals, 510k #: K-890556
- Sacred Crane TDP Lamp CQ-27, United Pacific Co., 510k #: K-991503
- TDP Therapy, I.E.C. Health Products, 510k #: K-875052

(a)(4)
Description of the TDP CQ-27 Heat Lamp.
The TDP CQ-27 Heat Lamp is used to provide topical heating to the body. The TDP CQ-27 Heat Lamp is specially engineered using a rare earth ceramic plate. Emission spectrum ranges from 2 to 50 microns. The emission heating plate should be replaced after 1,200 to 1,500 hours of usage. 110 volt power, 250 watts. Floor standing model includes 60 minute timer, 2 safety fuses, and 4 swivel casters. The height of the device head can be adjusted from 12" to 60" (above the floor level). Warm up time before use is 10 to 15 min.

(a)(5)
The TDP CQ-27 Heat Lamp may be used for 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 the relaxation of muscles. In addition, the TDP CQ-27 Heat Lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

..... continued on next page (Page 6c)

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PRE-MARKET NOTIFICATION 510(k) SUMMARY ..... continued from previous page

(a)(6)
The TDP CQ-27 Heat Lamp meets the general specifications, criteria, and effectiveness for heat lamps. The TDP CQ-27 Heat Lamp also has the same technological characteristics as the predicate devices identified in paragraph (a)(3). The TDP CQ-27 is identical in size, appearance, function, and operation; and uses the same heating plate method and design and same method of power and output as these predicate devices.

(b)(1)(2)(3)
Substantial equivalence is not based on an assessment of performance data.

(c)
This Pre-Market Notification 510(k) Summary includes these 3 pages (Pages 6a, 6b, and 6c) in total.

Kyung P. Riihimaki

Mrs. Kyung P. Riihimaki, President

March 5, 2001

Date

Premarket Notification (510(k) Number): K-003538

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2001

Kyung Riihimaki
Lhasa Medical, Inc.
234 Libbey Parkway
Weymouth, MA 02189

Re: K003538
Trade/Device Name: TDP CQ-27 Heat Lamp
Regulation Number: 890.5500
Regulatory Class: II
Product Code: ILY
Dated: March 5, 2001
Received: March 7, 2001

Dear Mrs. Riihimaki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Division Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K-003538

Device Name: TDP CQ-27 Heat Lamp

Indications for Use:

The TDP CQ-27 Heat Lamp may be used for 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 the relaxation of muscles. In addition, the TDP CQ-27 Heat Lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

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

Concurrence of CDRH, Office of Device Evaluations (ODE)

[signature] for [signature]
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003538

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.109)