K013197

AUG 2 9 2002

PAGE 1 OF 2

LHASA MEDICAL, INC.

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

September 21, 2001 Page 6a

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 fax: 1-781-335-6296 phone: (781) 340-1071
Contact Person:	Mrs. Kyung P. Riihimaki
Date Summary Prepared:	September 21, 2001

(a)(2)

Name of Device:	WS-501 Heat Lamp
Common or Usual Name:	Infrared Heating Lamp
Product Code:	ILY
Classification:	Class II
510(k) Number:	K-

..... 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 WS-501 Heat Lamp is similar and/or 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:

- WS Portable Infrared Heat Lamp, CAI Industries, 510k # K-954577
- TDP CQ-27 Heat Lamp, Lhasa Medical, Inc, 510k #: K-003538
- Firard II TDP Lamp, Helio Medical Supplies, 510k #: K-960036

(a)(4)
Description of the WS-501 Heat Lamp.
The WS-501 Heat Lamp is used to provide topical heating to the body. The WS-501 Heat Lamp is specially engineered using a rare earth ceramic plate. Emission spectrum ranges from 0.5 to 13,500 microns. The emission heating plate life ranges from 5,000 to 10,000 hours of usage. 110 volt power, 20 watts with hi and low switch. Hand held model also features a table top stand. Warm up time before use is 3 to 5 min.

(a)(5)
The WS-501 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 WS-501 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 WS-501 Heat Lamp meets the general specifications, criteria, and effectiveness for heat lamps. The WS-501 Heat Lamp also has the same technological characteristics as the predicate devices identified in paragraph (a)(3). The WS-501 is similar in 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 — September 21, 2001

Mrs. Kyung P. Riihimaki, President — Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

Kyung P. Riihimaki, President
Lhasa Medical, Inc.
234 Libbey Parkway
Weymouth, Massachusetts 01289

Re: K013197
Trade/Device Name: WS-501 Heat Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Infrared
Regulatory Class: II
Product Code: ILY
Dated: May 31, 2002
Received: June 3, 2002

Dear Mrs. Riihimaki:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
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-

Device Name: WS-501 Heat Lamp

Indications for Use:

The WS-501 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 WS-501 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)

for Mark N Melkerson

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

510(k) Number K013197

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