JUN 6 - 2005

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510 (k) Premarket Notification Summary

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Device Name:
Proprietary Name: Xinfeng Lamp
Common/Usual Name: Infrared Lamp
Device Name: Infrared Lamp
Product Code: ILY
Classification: Class II

Predicate Device:
TDP CQ-27 Heat Lamp
Establishment: LHASA Medical Inc.

K043558
Additional Information for Xinfeng Heating Lamp

Regulation Number: 890.5500
Product Code: ILY
510(k) Number: K003538
Registration Number: 1222811
Owner/Operator Number: 9003816

Description of the Xinfeng Heating Lamps:

Xinfeng Heating Lamp, including 3 different models CQ-27, CQ-36 and CQ-55A, consists of heating head, swing arm, control box and pedestal with extension. It is used to provide topical heating to the body and is specially engineered using a plate. Model CQ-27 and CQ-36 have only one operating mode, while model CQ-55A has two operating modes. Emission spectrum ranges from 5 to 25 microns for models CQ-27, CQ-36 and state I of CQ-55A. Model CQ-55A also includes an additional operating state (State II) having an emission range of 2 to 50 microns. The emission heating plate shall be replaced after 1,000 hours of usage.

Indications for use

Xinfeng Heating Lamp, including 3 different models CQ-27, CQ-36 and CQ-55A, is an infrared lamp that emits the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, to temporarily increase local blood circulation, and to temporarily relieve minor muscle and joint pain and stiffness. The lamps may also help to relieve minor pain associated with muscle spasms, minor sprains and strains, and minor muscular back pain.

Substantial Equivalence Information

Xinfeng CQ-27, CQ-36 and CQ-55A Heating Lamps are generally equivalent to CQ-27 Heat Lamp (K003538) manufactured by Lhasa Medical, Inc. on label and labeling, materials used, specifications and intended use. All the technical data are tested according to **GB 9706.1-1995** which is identical to **IEC 60601-1**

The equivalence information is focused on intended use, materials and specifications. The Xinfeng Heating lamps use 110V voltage, 5 casters and 2 fuses. The use age is 1000 hours and the skin temperature is at 40~45^{0}C in a treatment distance from heating unit to treatment surface 8" to12" for models CQ-27, CQ-36 and state I of CQ-55A, but for state II operating mode of CQ-55A it is 10" to12".

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Additional Information for Xinfeng Heating Lamp

Table 1.
Predicate device: TDP CQ-27 Heat Lamp manufactured by Lhasa Medical, Inc.
The new device: Xinfeng Heating Lamp CQ-27

Item	The predicate device			The new device		
Components	heating head, swing arm, control box and pedestal with extension			heating head, swing arm, control box and pedestal with extension		
Power Frequency	50/60 Hz			50/60 Hz		
Power	≤ 250 W			≤ 250 W		
Spectrum Ranges	2 to 50 microns			5 to 25 microns		
Warming Up Time	15 minutes			15 minutes		
Total Working Hours	1,200 to 1500 hours			1,000 hours		
Operating Timer	Up to 60 minutes			Up to 60 minutes		
Number of Fuse	2			2		
Inner Cover Diameter	12 cm			12 cm		
Number of Casters	4			5		
Skin Temperature (^{0}C)	The distance from the lamp head and the result					
	8"	10"	12"	8"	10"	12"
	45^{0}C	43^{0}C	41^{0}C	45^{0}C	43^{0}C	41^{0}C

Table 2.
Predicate device: TDP CQ-27 Heat Lamp manufactured by Lhasa Medical, Inc.
The new device: Xinfeng Heating Lamp CQ-36

Item	The predicate device			The new device		
Components	heating head swing arm standard control box pedestal with extension			heating head swing arm control box with digital display pedestal with extension		
Power Frequency	50/60 Hz			50/60 Hz		
Power	≤ 250 W			≤ 250 W		
Spectrum Ranges	2 to 50 microns			5 to 25 microns		
Warming Up Time	15 minutes			15 minutes		
Total Working Hours	1,200 to 1500 hours			1,000 hours		
Operating Timer	Up to 60 minutes			Up to 95 minutes		
Number of Fuse	2			2		
Inner Cover Diameter	12 cm			16.6 cm		
Number of Casters	4			5		
Skin Temperature (^{0}C)	The distance from the lamp head and the result					
	8"	10"	12"	8"	10"	12"
	45^{0}C	43^{0}C	41^{0}C	44^{0}C	42^{0}C	40^{0}C

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Additional Information for Xinfeng Heating Lamp

Table 3.
Predicate device: TDP CQ-27 Heat Lamp manufactured by Lhasa Medical, Inc.
The new device: Xinfeng Heating Lamp CQ-55A

Item	The predicate device	The new device
Components	heating head with one heating unit swing arm standard control box pedestal with extension	heating head with three heating unit swing arm control box with digital display pedestal with extension
Power Frequency	50/60 Hz	50/60 Hz
Power	≤ 250 W	≤ 280 W
Warming Up Time	15 minutes	15 minutes
Total Working Hours	1,200 to 1500 hours	1,000 hours
Operating Timer	Up to 60 minutes	Up to 95 minutes
Number of heating head	1	3
Number of Fuse	2	2
Inner Cover Diameter	12 cm	8 cm
Number of Casters	4	5

Spectrum Ranges State I	2 to 50 microns			5 to 25 microns		
Skin Temperature State I (^{0}C)	The distance from the lamp head and the result					
	8"	10"	12"	8"	10"	12"
	45^{0}C	43^{0}C	41^{0}C	44^{0}C	42^{0}C	41^{0}C

Spectrum Ranges State II	2 to 50 microns			2 to 50 microns		
Skin Temperature State II (^{0}C)	The distance from the lamp head and the result					
	8"	10"	12"	8"	10"	12"
	45^{0}C	43^{0}C	41^{0}C	47^{0}C*	44^{0}C	43^{0}C

*47^{0}C exceeds the safe temperature range and that model CQ-55A should be positioned at least 10 inches from the body surface to be treated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 - 2005

Chongqing Xinfeng Medical Instrument Company, Ltd.
C/o Mr. George Su
Crosslinks International, Inc.
1800 Century Park East, Suite 600
Century City, California 90067

Re: K043558
Trade/Device Name: Xinfeng Heat Lamps, Models CQ-27, CQ-36, CQ-55A
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: May 26, 2005
Received: May 26, 2005

Dear Mr. Su:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043558
Additional Information for Xinfeng Heating Lamp

Indications for Use

510(k) Number (if known): K043558

Device Name: Infrared Lamp

Indications for Use:

Xinfeng Heating lamp, including CQ-27, CQ-36 and CQ-55A, is an infrared lamp that emits the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, to temporarily increase local blood circulation, and to temporarily relieve minor muscle and joint pain and stiffness. The lamps may also help to relieve minor pain associated with muscle spasms, minor sprains and strains, and minor muscular back pain.

Prescription Use √ (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)

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

510(k) Number K043558