K020851
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SEP 23 2002

Pre-market Notification 510(K) Summary

1.0 Submitter Name and Address:

Mike Luo, President, Ph.D.
C&H International Inc.
1202 Melford Drive
Houston, TX 77077, USA
Phone: (281) 352-1880; Fax: (281) 679-7224

Date Prepared: June 17, 2002 (revised from March 9, 2002)

2.0 Name of Device:

Proprietary Name:	TDP CQG-111A, CQG-111B, CQG-222A, CQG-222B, CQG-270A, CQG-270B, and CQG-222D Heat Lamps
Common/Usual Name:	Infrared Heating Lamp, TDP CQ-27 Lamp
Product Code:	IL Y
Classification:	Class II
510(K) Number (if known):	K020851

3.0 Predicate Device:

The TDP Lamps with Model No.: CQG-111A/B, CQG-222A/B, CQG-270A/B and CQG-222D are equivalent in design and performance to other brands of infrared heating lamps such as:

- TDP CQ-27 Lamp, Lhasa Medical Inc., 510(K)K003538
- Firard II TDP Lamp, Helio Medical Supplies, 510(K)K960036
- TDP Infrared Heat Lamp, Toxicology Professionals, 510(K)K890556
- Sacred Crane TDP Lamp CQ-27, United Pacific Co., 510(K)K991503
- TDP Therapy, I.E.C. Health Products, 510(K)K875052

4.0 Description of the TDP Lamps:

The TDP CQG-111A/B, CQG-222A/B, CQG-270A/B and CQG-222D lamps can be used to emit topical heating to the body of human. The TDP Lamps are specially designed to use a curing plate that is made of a rare earth and minerals. Emission spectrum ranges from 1 to 25 microns. The life of emission curing plate is 1,000 to 1,500 hours. When the curing plate is used up to 1,000 hours, the treatment effect of the curing plate will gradually depressed. After the curing plate is used for 1,500 hours, it should be replaced with a new one. The device manufactured for the United States of America uses 110 volts power and 250 (or 275) watts. All models have 1 safety fuse, 4-swivel heater and a safety grilling

cover. All models include a 60-minutes timer. Only difference between Model "A" (or "D") and Model "B" is the control system. Model "A" (or "D") TDP is controlled with a mechanical system, but Model "B" TDP is controlled with an electronic system.

The TDP Lamps may be used for temporary relief of minor muscle, joint pain and stiffness, minor joint pain associated with arthritis, temporary increase in local circulation in the area that emission touches, and the temporary relaxation of muscles. The TDP lamps may also help to relief muscle spasms, minor sprains and strains, and minor muscular back pain.

The TDP Lamps manufactured by Chongqing Silicate Research Institute meets the general specifications, criteria, and effectiveness for heat lamps. The TDP Lamps also have the same technological characteristics as their predicate device such as TDP CQ-27 lamp.

5.0 Manufactory:

The first TDP Lamp was invented by Chongqing Silicate Research Institute (CSRI) in 1985. The former president of Chongqing Silicate Research Institute presented the TDP lamp at the 1986 Zagreb International Fair and the 1986 Brussels Eureka World Fair for Invention, and won a gold and a silver medal, respectively. Chongqing Silicate Research Institute submitted a patent application for the technology of the TDP lamp in 1987. The application was approved by Chinese Patent Bureau in December 1992. Before Nov. 1996, the TDP lamps marketed in the USA contained the curing plates manufactured by CSRI. After Nov. 1996, CSRI stopped supplying its curing plates to Chongqing Bashan Instrument Factory which is the manufacturer for most of TDP lamps marketed in the USA.

Signature, Date:

Mike Luo June 20, 2002

Mike Luo, President, Ph.D.
C&H International Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Mike Luo, Ph.D., President
C&H International Inc.
1202 Melford Drive
Houston, Texas 77077

Re: K020851
Trade/Device Name: TDP Lamp, Models CQG-111A/B, CQG-222A/B/D, CQG-270A/B
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 20, 2002
Received: June 25, 2002

Dear Dr. Luo:

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.

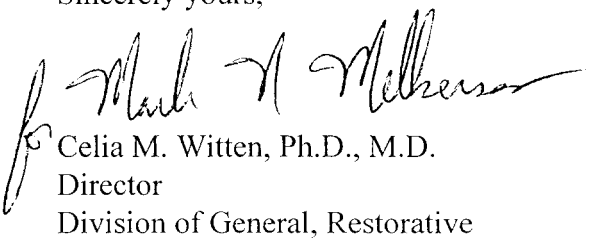
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

Applicant: C&H International Inc.

510(k) Number (if known): K020851

Device Name: TDP CQG-111A/B, CQG-222A/B/D and CQG-270A/B Heat Lamp

Indications For Use:

The TDP CQG-111A/B, CQG-222A/B, CQG-270A/B and CQG-222D 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 relaxation of muscles. In addition, the 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 Evaluation (ODE)

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

510(k) Number K020851

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

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