510(K) SUMMARY

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FEB 16 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. **Submitter's Name: CHUNG CHENG ELECTRIC HEATING CO., LTD.**

Address: NO. 39 HUAN KUNG RD., YUNG KANG INDUSTRIAL AREA, YUNG KANG CITY, TAINAN HSIEN, TAIWAN

Phone: +886-6-2314078

Fax: +886-6-2330916

Contact: Mr. C.T. Chang/President

2. **Device Name :**

Trade Name: **"CHUNG CHENG " Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810**

Common Name: Infrared Heating Lamp

Classification name Lamp, Infrared

3. **DEVICE CLASS** **"CHUNG CHENG " Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810** have been classified as

Regulatory Class: II

Product Code: ILY

Panel : Physical Medicine

Regulation Number: 21CFR 890.5500

4. **Predicate Device:** The predicate device is the

- **FIRARD II/ TDP LAMP (K960036)** marketed by **HELIO MEDICAL SUPPLIES, INC.**

5. **Device Description:** The **"CHUNG CHENG " Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810** can be used to emit topical heating to the body of human. The device make use of a "All In One" Automatic control Temperature Ceramic Semiconductor. Emission spectrum ranges from 4 to 14 microns. The device uses 120Vac as power source & 800W . it meets the related requirement of IEC 60601-1 Electrical Safety.

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6. Intended Use: The **"CHUNG CHENG " Far Infrared Ray healthful Lamp (o Medical FIR Radiator) Model #CH-8810** may be used for th temporary relief of minor muscle and joint pain and stiffness, the temporary relief of 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.

7. Performance Summary: The device conforms to applicable standards includes IEC 60601-1, IEC 60601-1-2 & related standards----etc.

8. Conclusions:

The **"CHUNG CHENG " Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810** has the same intended use and similar technological characteristics as the **FIRARD II/ TDP LAMP (K960036)** marketed by **HELIO MEDICAL SUPPLIES, INC.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **"CHUNG CHENG " Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2006

Chung Cheng Electric Heating Co., Ltd.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, Arizona 86001

Re: K053376
Trade/Device Name: "CHUNG CHENG" Far Infrared Ray healthful Lamp (or Medical FIR Radiator) Model #CH-8810
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: January 26, 2006
Received: February 6, 2006

Dear Ms. Reich:

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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053376

Device Name: "CHUNG CHENG " Far Infrared Ray healthful Lamp
(or Medical FIR Radiator) Model #CH-8810
CHUNG CHENG ELECTRIC HEATING CO., LTD.

Indications For Use:

The device may be used for the temporary relief of minor muscle and joint pain a stiffness, the temporary relief of joint pain associated with arthritis, the temporar increase in local circulation where applied, and relaxation of muscles. In additio the lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number_____