RichWay International, Inc.
1314 S. King St., Ste. 520
Honolulu, HI 96814
PH: 808-589-2800 FAX: 808-597-1651

510(k) SUMMARY

RichWay International, Inc.'s Bio-Mat 2000

Submitter's Contact Information

Name: LeRoy Klima

Address: RichWay International, Inc.
1314 S. King St., Ste.520
Honolulu, Hawaii 96814

Phone: (808)589-2800
Fax: (808)597-1651

Name of Device and Name/Address of Sponsor

Trade Name: Bio-Mat 2000

Sponsor Contact: Calvin Kim
RichWay International, Inc.
1314 S. King St., Ste. 520
Honolulu, Hawaii 96814

Common or Usual Name: Infrared heat pad for temporary relief of body aches and pains.

Classification Name: Lamp, Infrared, Therapeutic Heating (ILY) per 21 C.F.R. }890.5500

Device Trade Name	Manufacturer
Chung Cheng Electric Far Infrared Healthful Lamp	Chung Cheng Electric Heating Co
Lightwave Infrared Lamp	Skytech Enterprises, Inc.
LumiWave 1x4 Infrared Therapy Device	BioCare System, Inc

AutoPrism Infrared Lamp	Rich-Mar Corporation
KenkoWave Infrared Pain Treatment System	Kaylight Corporation
Health O Meter Electric Heating Pad with Massage	Sunbeam Health Division

Intended Use / Indications for Use

The Bio-Mat is indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis; the temporary relief of muscle spasms, minor sprains and strains, and minor muscular back pain; the relaxation of muscles; and the temporary increase of local circulation where applied.

Technological Characteristics

The Bio-Mat is an electrically powered mattress pad that applies infrared heat to the user's body for the temporary relief of minor body aches and pains. A control panel allows the user to turn the product on/off, modify the temperature, and set the product's timer.

Performance Data

In all instances, the Bio-Mat functioned as intended, and passed the **UL** (Underwriters Laboratories) detailed/extensive tests (see Attachment 18A). These tests included the function, performance, safety, and durability of the Bio-Mat. A total of 70 Bio-Mats were eventually sent to the Underwriters Laboratories which indicates how complete the testing was.

Substantial Equivalence

The Bio-Mat is as safe and effective as the predicate devices identified above. The Bio-Mat has the same intended uses and similar indications as the predicate devices. The technological differences between the Bio-Mat and the predicate devices that used infrared ray technology do not raise new questions of safety and effectiveness (see Substantial Equivalence Chart).

Indications for Use

510(k) Number _____

Device Name: Bio-Mat Mattress

Indications for Use:

The Bio-Mat is indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis; the temporary relief of muscle spasms, minor sprains and strains, and minor muscular back pain; the relaxation of muscles; and the temporary increase of local circulation where applied.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _X_____ (21 CFR 801 Subpart C)

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

510(k) Number k022534

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 8 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RichWay International, Inc
% Mr. LeRoy Klima
Consultant
1314 South King Street, Suite 520
Honolulu, Hawaii 96814

Re: K072534
Trade/Device Name: Bio-Mat Mattress
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered heating pad, Infrared lamp
Regulatory Class: Class II
Product Code: IRT
Dated: January 03, 2008
Received: January 08, 2008

Dear Mr. Klima:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure