AUG 26 2005

K051816

9. 510(k) Summary

510(k) SUMMARY
BIOCARE SYSTEMS, INC – LumiWave 1X4 Infrared Therapy Device

SUBMITTER INFORMATION

Company name / address: Reglera LLC
518 17th Street
Suite 1350
Denver, CO 80202

510(k) contact name / numbers: **Clay Anselmo**
Phone: 800-341-4255 or 303.223.4303
Fax: 303-832-6700
anselmoc@reglera.com

Date summary prepared: 6/9/05

DEVICE IDENTIFICATION

Trade names: LumiWave 1X4 Infrared Therapy Device

Common name: LumiWave 1X4 Infrared Therapy Device

Classification name: Infrared Lamp

MODIFIED FROM DEVICE:

Trade name: BioCare System's PremIR 818
510(k) number: K042532

DEVICE DESCRIPTION

The LumiWave 1X4 Infrared Therapy Device is an over-the-counter, infrared-therapy device, designed to emit energy at infrared frequencies to provide topical heating. The LumiWave 1X4 Infrared Therapy Device provides infrared therapy through the use of an efficient and easy to use set of 4 small pods that delivers infrared light for the purpose of elevating tissue temperature to treat living tissue in the body. Infrared light is delivered to the tissue through 49 Gallium Aluminum Arsenide (GaAlAs) Light Emitting Diodes (LEDs) (per pod) distributed under the each pod cover of the LumiWave 1X4 Infrared Therapy Device. The LEDs used in the LumiWave 1X4 Infrared Therapy Device have average wavelengths of between 880 nm and 893 nm depending on temperature.

INDICATIONS FOR USE

BioCare System's infrared therapy products emit energy in the infrared spectrum for the purposes of elevating tissue temperature; for temporary relief / reduction of minor muscular pain, minor muscular back pain and minor joint pain and stiffness. Additionally, these products are intended

to provide a temporary increase in local blood circulation and provide temporary relief of muscle spasms and minor sub-acute or chronic pain associated with arthritis, sprains or strains.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The following primary characteristics of the LumiWave 1X4 Infrared Therapy Device are substantially equivalent to the BioCare PremIR 818.

- Indications for Use
- Wavelength of the diode utilized
- Waveform
- Power supply and specifications
- Energy source
- Device type
- Delivered energy per unit area

PERFORMANCE DATA

Delivered Energy: 12 – 56 mW/cm^2

	HIGH Mode	LOW Mode
Central Wavelength:	900 nm	899 nm
Mean Wavelength:	893 nm	890 nm
Minimum Wavelength:	824 nm	822 nm
Maximum Wavelength:	941 nm	934 nm

Note: maximum and minimum wavelengths were calculated using the area under the distribution which contains 99.7% of the population (+/- 3 sigma)

Complies with EN 60601-1-2, Electromagnetic Compatibility
Complies with EN 60601-1, General Electrical Safety

The Thermal control circuit in each pod provide for regulation of skin temperatures to between 40 and 45 degrees C (average of approximately 42 C in HIGH Mode and 41 C in LOW Mode).

CONCLUSION

The LumiWave 1X4 Infrared Therapy Device is substantially equivalent to the device it was modified from, the PremIR 818.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

BioCare Systems, Inc.
c/o Mr. Clay Anselmo
Reglera LLC
518 17th Street, Suite 1350
Denver, Colorado 80202

Re: K051816
Trade/Device Name: LumiWave 1X4 Infrared Therapy Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 16, 2005
Received: August 17, 2005

Dear Mr. Anselmo:

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.

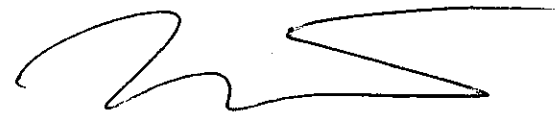
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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,



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): _____

Device Name: LumiWave 1X4 Infrared Therapy Device

Indications for Use:

BioCare system's infrared therapy products emit energy in the infrared spectrum for the purposes of elevating tissue temperature; for temporary relief / reduction of minor muscular pain, minor muscular back pain and minor joint pain and stiffness. Additionally, these products are intended to provide a temporary increase in local blood circulation and provide temporary relief of muscle spasms and minor sub-acute or chronic pain associated with arthritis, sprains or strains.

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

(Posted November 13, 2003)

510(k) Number K051816