

K042532

DEC 13 2004

9. 510(k) Summary

510(k) SUMMARY
BIOCARE SYSTEMS, INC – PremIR 818

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: 8/3/04

DEVICE IDENTIFICATION

Trade names: PremIR 818

Common name: PremIR 818 Infrared Therapy Device

Classification name: Infrared Lamp

PREDICATE DEVICES

Trade name: LightForce Super Nova
510(k) number: K022888 and K001179

Trade name: Quantum WARP 10 Light Delivery System
510(k) number: K032229

DEVICE DESCRIPTION

The PremIR 818 is an over-the-counter, infrared-therapy device, designed to emit energy at infrared frequencies to provide topical heating. The PremIR 818 provides infrared therapy through the use of an efficient and easy to use hand held pad that delivers infrared light for the purposes of elevating tissue temperature to treat living tissue in the body. Infrared light is delivered to the tissue through 144 Gallium Aluminum Arsenide (GaAlAs) Light Emitting Diodes (LEDs) distributed under the face plate of the PremIR 818. The LEDs used in the PremIR have average wavelengths of between 880 nm and 884 nm.

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 PremIR 818 device are substantially equivalent to the LightForce Super Nova device.

- Indications for Use
- Wavelength of the light utilized
- Waveform
- Power supply and specifications
- Energy source
- Number of LEDs
- Device type

The following primary characteristics of the PremIR 818 device are substantially equivalent to the Quantum WARP 10 device.

- Indications for Use
- Wavelength of the light utilized
- Energy source
- Energy delivery
- Device type
- Power Output

PERFORMANCE DATA

Delivered Energy: 35 – 56 mW/cm²
Central Wavelength: 884 nm
Mean Wavelength: 881 nm
Minimum Wavelength: 831 nm
Maximum Wavelength: 937 nm

Complies with IEC 601-1-2, Electromagnetic Compatibility
Complies with UL 60601-1, General Electrical Safety

Maintains skin (treatment) temperatures between 40 and 45 degrees C for greater than 10 minutes

CONCLUSION

The PremIR 818 is substantially equivalent to the LightForce Super Nova and the Quantum WARP 10 Light Delivery System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Reglera LLC
C/o Mr. Clay Anselmo
518 17th Street
Suite 1350
Denver, Colorado 80202

Re: K042532
Trade/Device Name: PremIR 818
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 2, 2004
Received: September 17, 2004

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.

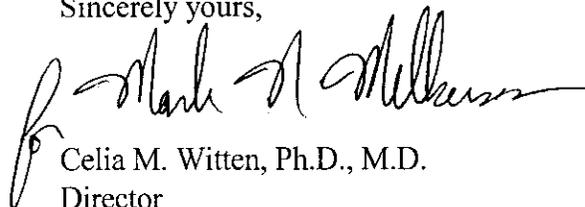
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Clay Anselmo

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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

Indications for Use

510(k) Number (if known): K042532

Device Name: PremIR 818

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)

[Handwritten Signature]
(Division Sign-Off)

Division of General, Restorative, and Neurological Devices, Page ___ of ___

(Posted November 13, 2003)

510(k) Number K042532