DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2017

Wellray Medical Laser, Inc.
Mr. Richard DeRoberts
Chief Executive Officer
216 Moores Run Rd.
Wardensville, West Virginia 26851

Re: K170068
Trade/Device Name: Softcure 96
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: February 8, 2017
Received: February 8, 2017

Dear Mr. DeRoberts:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170068

Device Name
Softcure TM 96

Indications for Use *(Describe)*
The Softcure TM 96 is intended to emit energy in the visible spectrum (red 635nm) to provide topical heating for the purpose of elevating tissue temperature for the temporary relief/reduction of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

A. Submitter:

Wellray Medical Laser, Inc.
216 Moores Run Rd.
Wardensville, WV 26851
USA

Phone: 304-874-4209
Fax: 304-874-4209

Contact: Mr. Richard O. DeRoberts CEO

Date prepared: January 4, 2017

B. Device Names:

Proprietary Name:	Softcure™ 96
Common/Usual Name:	Infrared Therapeutic Heating Lamp
Classification Name:	Infrared Lamp

C. Predicate Devices

Biocare ™ Lumiwave® K051816
Sunetics Laser Brush, LHB 12 K121920
Anodyne® Therapy 480 Pro K931261
Biophotas Celluma ™ K131113

D. Device Description:

The Wellray® Medical Laser Softcure™ 96 is a therapeutic device using wavelengths of monochromatic light produced by semiconductor laser diodes to treat a variety of musculoskeletal concerns. The Softcure ™ 96 is a portable and wearable, battery powered, software controlled device intended for use on the body such as the back, legs, chest, arms or other areas where therapeutic light may be beneficial. A flexible pad, drawing power through an electrical cable from a carry able battery pack, emits red (635nm) light by means of semiconductor laser diodes to the desired body area. The flexible pad is designed to conform to the contour of the treatment site providing uniform treatment dosage over non-planar body physique. The semiconductor laser diodes are monitored for temperature and light output by a microprocessor and cooled by variable speed fans to ensure the optimum light output. The lasers are allowed to energize only when four separate failsafe monitoring systems sense that the flexible pad is brought into close contact with the user's body. These failsafe systems include capacitive proximity sensors, body temperature sensors, an ambient light sensor and reference voltage monitoring.

E. Intended Use:

The Softcure ™ 96 is intended to emit energy in the visible spectrum (red 635nm) to provide topical heating for the purpose of elevating tissue temperature for the temporary relief/reduction of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.

F. Substantial Equivalence:

The Softcure™ 96 is substantially equivalent to the Biocare ™ Lumiwave® - K051816, the Sunetics Laser Brush, LHB 12 - K121920, the Anodyne® Therapy 480 Pro - K931261 and the Biophotas Celluma ™ - K131113 as summarized in the following table. The Softcure ™ 96 and the predicate devices have the same intended use, the same diffused light characteristic, the same software control, the same use of a treatment timer, the same over-the-counter (OTC) use, the same method of administration (topical), the same configuration (pads/pods), and the same electrical safety.

Predicate Device	Manufacturer	510(k) Number
Lumiwave®	Biocare ™	K051816
Laser Brush, LHB 12	Sunetics	K121920
480 Pro	Anodyne® Therapy	K931261
Celluma ™	Biophotas	K131113

Where the Softcure ™ 96 differs is that it is wearable and is powered by a battery so that the user can move around the treatment site or home and perform light tasks. It also differs in that it has multiple failure detection/shut off controls and multiple failsafe monitoring systems.

The differences identified above do not impact adversely the Safety and Effectiveness of the Softcure ™ 96 device.

Performance data have been included to demonstrate that the Softcure ™ 96 device meets its specifications, and functions safely.

G. Performance Testing Bench

Electrical safety and functional performance testing were conducted on the Softcure™ 96 demonstrating that the device is compliant with FDA 21 CFR J 1040.10 and 1040.11 standards, AAMI/ANSI ES 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety and Essential Performance AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012), IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests, 2007-03.

H. Performance Testing Non-Clinical

The use of light energy to generate heat for therapeutic use has been well documented and is a generally accepted alternative treatment modality for the temporary relief of pain and tissue repair.

The Softcure™ 96 is capable of achieving therapeutic heat temperature of 40 – 45 degrees centigrade as accepted by the FDA. An increase in topical heating of the tissue level by at least 5 degrees centigrade was reached within one (1) minute. The therapeutic temperature range was maintained for at least ninety (90) minutes.

The temperature versus time measurements were conducted on 8 subjects at various physical locations, i.e., leg, neck, back and shoulder. The pre-exposed topical skin temperature ranged from 36 to 39 degrees centigrade. These data demonstrate that the Softcure™ 96 meets the generally accepted topical

temperature range for therapeutic heat of 40-45 degrees centigrade during the recommended treatment time.

I. Conclusion

The Softcure ™ 96 device is substantially equivalent to the predicate devices K051816, K121920, K931261 and K131113.