K102375

510(k) Summary for the Lucia

FEB 25 2011

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92(c).

1. General Information

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Summary Preparation Date: August 19, 2010

2. Names

Device Trade Name: Lucia
Common Name: Infrared lamp
Classification Name: Lamp, infrared, therapeutic, heating
Product Code: ILY (21 CFR 890.5500)
Panel: Physical Medicine

3. Predicate Device

LAPEX BCS (K081962), Meridian Co., Ltd.

4. Device Description

The Lucia has a hand-held treatment probe, is non-invasive, low level visible lamp that provides continuous heat therapy at fixed frequency. The System consists of a Drive Unit, Power Supply, controls and optional treatment probes

that contain the visible radiating elements. The Lucia generator automatically calculates energy output in relation to set treatment parameters. The parameters (treatment time, output power delivered) can be adjusted by using key, treatment specifications and menus. The progress of the treatment is displayed on the LCD display in real time. The Lucia generator operates simultaneous and independent management of outputs for connecting probes with laser sources from the Red wavelength. The Lucia generator is supplied with 2 completely independent outputs for using two treatment probes. The LCD displays operating parameters from both channels. This allows two operators to carry out laser therapy independently: just like having two separate instruments.

5. Indications for Use

The Lucia is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

6. Substantial Equivalence

The Lucia is substantially equivalent to the LAPEX BCS (K081962) which is also manufactured by Meridian Co., Ltd. The Lucia has the same intended use as and similar technological characteristics as the predicate device. The Lucia utilizes laser diodes to elevate tissue temperature to a range which is recognized to provide temporary relief of certain muscle and joints pains. The technological characteristics of the predicate device are exactly the same as the Lucia. The Lucia described in this 510(k) has the same intended use, indications for use, and technological characteristics as the currently cleared predicate device and is substantially equivalent to the identified predicate device.

7. Performance Data

Performance data was presented which showed that skin temperature was elevated as required for this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Meridian Co., Ltd.
% Research Practice Partners, Inc.
Vinod Podichetty, M.D.
3550 SW 148th Avenue, Suite 110
Miramar, Florida 33027

FEB 25 2011

Re: K102375
Trade/Device Name: Lucia
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: February 18, 2011
Received: February 22, 2011

Dear Dr. Podichetty:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102375

Device Name: Lucia

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102375