510(k) Summary for the Lutronic Corporation HEALITE II

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

JUN 19 2012

1. General Information

Submitter:

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Contact Person

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Summary Preparation Date: May 15, 2012

2. Names

Device Name: HEALITE II

Classification Name: Laser instrument, surgical, powered device:
GEX, ILY
FDA Class II category

Although this device is not a laser, the manufacturer believes this is the closest applicable classification name.

3. Predicate Devices

The HEALITE II system is substantially equivalent to the Omnilux Plus (K043317).

4. Device Description

The HEALITE II system is a light emitting diode (LED) with high spectral purity. This system is packaged with an LED head for the particular intended use of the system. The wavelength of the HEALITE II is 830 nm. Additionally there is a 590 nm aiming beam. The base unit contains power supply and control system. The user interface software allows the operator to access and control all device functions.

5. Indications for Use

The HEALITE II system is intended for the following:

For use in temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

6. Substantial Equivalence

The HEALITE II system is substantially equivalent to the Omnilux Plus (K043317). The intended use and technological characteristics of the HEALITE II system are virtually identical to the intended use and technological characteristics of the predicate devices. Any differences between the HEALITE II and the equivalent devices have no significant influences on safety or effectiveness of the HEALITE II system. Therefore, the HEALITE II system is substantially equivalent the predicate systems.

7. Performance Data

None presented.

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

JUN 19 2012

Lutronic Corporation
% Lutronic Inc.
Jhung Won Vojir, Ph.D.
CEO
6 Neshaminy Interplex, Suite 207
Trevose Pennsylvania 19053

Re: K113668
Trade/Device Name: Healite II System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: June 04, 2012
Received: June 05, 2012

Dear Jhung Won Vojir:

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.

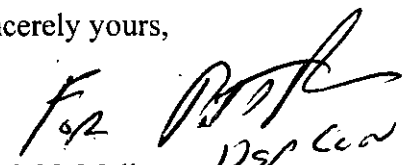
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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): K113668

Device Name: HEALITE II

Indications for Use:

The HEALITE II is intended for the following:

For use in temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

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