 K103511

510(k) SUMMARY

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Applicant	LiteCure, LLC 250 Corporate Blvd., Suite B Newark, Delaware 19702 Tel: 302-709-0408 Fax: 302-709-0409
Date	November 11, 2010
Correspondent	Liang Lu Quality and Regulatory Manager
Device Name	LiteCure Therapy System, Model LTS-1500
Classification	Infrared Lamp, 21 CFR 890.5500
Predicate:	• K070400, LC THERAPY, MODEL LCT-1000, LiteCure, LLC • K091497, K-LASER K-1200, MODEL 12 W, ELTECH, S.R.L.
Description	LiteCure Therapy System, Model LTS-1500 is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight handpiece. Activation occurs when the operator enables the laser and presses the foot/finger switch. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.
Intended Use	LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.
Contraindications	• Do not apply infrared light to abdominal or lumbosacral points in pregnant females. • Do not apply infrared light to the epiphyseal lines in children. • Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers. • Do not apply infrared light over the thyroid gland, ovaries and testicles. • Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not Limited to certain types of steroids.

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Warning	• Warning: Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous. • NEVER look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated WITH or WITHOUT the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. • DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure. • DO NOT attempt to gain access to any internal device component. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury. • AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N_2O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. • FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.
Cautions:	• Never allow untrained personnel to operate this advice unless directly supervised by a properly trained and experienced individual • The protective eyewear supplied with this device has an optical density rating >5 in the 350nm~2000nm (see specification sheet) region. All personnel present during device operation must ware this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.

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Caution continued	• Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser. • Place "Laser in use" signs at location entrances where people will use the LiteCure, LLC. laser device. • Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the wand or fiber optic. • Never leave this device in the READY mode unattended. See the STANDBY to READY Mode in the Operations section of this manual. • Remove the key from the device's key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions. • Turn the device off before relocating equipment in the same vicinity. • Never press the foot/finger switch without first verifying the safe orientation and proper positioning of the handpiece and distal end of the optical fiber and ensuring compliance to all safety precautions. • During any laser procedure, do not allow any nonessential personnel into the treatment area. • Never allow the untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual. • ALWAYS clean the SMA fiber tip before inserting into the SMA emission port. A dirty tip could result in damage to the unit. • Federal law (USA) restricts this device to sale by or on the order of a physician.
Substantial Equivalency Information	The LiteCure Therapy System, Model LTS-1500 is as safe and effective as the predicate devices. The LiteCure Therapy System, Model LTS-1500 has the same intended uses and similar indications, technological characteristics (such as wavelength, laser safety class, etc), and principles of operation as its predicate device. The minor technological differences between the LiteCure Therapy System, Model LTS-1500 and its predicate devices raise no new issues of safety or effectiveness. Thus, the LiteCure Therapy System, Model LTS-1500 is substantially equivalent to the device it was modified from, MODEL LCT-1000, and another predicate device, K-LASER K-1200.
Technological Characteristics	The device is subject to the following voluntary consensus standards: • IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (2nd Edition); • IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004); • IEC 60601-2-22 1995, 2nd Edition, "Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment". • IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements.

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

LiteCure, LLC
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Re: K103511
Trade/Device Name: LiteCure Therapy System, Model LTS-1500
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: December 28, 2010
Received: January 03, 2011

Dear Mr. Lu:

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): K103511

Device Name: LiteCure Therapy System, Model LTS-1500

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

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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