

K123177

510(k) Summary Pursuant to 21 CFR 807.92

JUL 3 2013

1. Submitted By: LaserStim, Inc.
C/O FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654
3. Product: StimLase 2000 System
Regulation: 890.5500 Infrared Lamp
Regulation: 882.5890 Transcutaneous electrical nerve
stimulator for pain relief
Class II
Product Code: ILY, GZJ
4. Common/Trade Name:
StimLase 2000 System
Heat Lamp and TENS Device
5. Date: June 30, 2013

Description:

The StimLase 2000 System is a therapeutic heating device with the capability to provide simultaneous or separate electrotherapy. The system consists of a console with selector settings, a footpedal control, and a laser wand. The unit can also accommodate two disposable OEM carbon electrodes for electrical stimulation therapy.

Intended Use:

Heat Lamp Therapy Feature:

The StimLase 2000 System is intended to be used for topical heating of tissue for the purpose of temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasms. The unit may be used for temporary increase in local blood circulation and/or the temporary relaxation of muscles.

Electrotherapy Feature:

The StimLase 2000 System is intended to be used for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Technological Characteristics:

The StimLase 2000 System is a therapeutic heating device with the capability to provide simultaneous or separate electrotherapy. The system consists of two major components, a base power control console and a hand held laser wand. The unit can also accommodate two disposable OEM carbon electrodes for electrical stimulation therapy.

The base power control console contains a key lock, a calibration port, a power adjustment dial, indicator lamps, and a touch-screen display. Power output can be adjusted from 0 to 550 mW. A foot switch is employed to activate the console. The gallium arsenide semiconductor laser diode is contained in the 7.5 inch hand held laser probe, which is used to apply infrared lamp treatment. The electrical stimulation therapy can be used separately or in conjunction with the therapeutic heating.

The StimLase 2000 System meets all requirements in 21 CFR§1040.10, 21 CFR§1040.11, and 21 CFR§1010 requirements for safety, performance, design, and labeling. In addition, the product has been tested to comply with IEC 60601 and IEC 60825.

Substantial Equivalence:

The StimLase 2000 System therapeutic heating feature is substantially equivalent to the Luminex Infrared Lamp System (K082969) and the Mettler Sys*Stim 240, ME 240 Combination Neuromuscular Stimulator and Low Level Light Therapy device (K113017).

Each of the predicate devices have similar technical features, indications for use, and the safety and effectiveness of the devices is equivalent.

Conclusions:

The predicate devices and the StimLase 2000 System share similar indications, technology, and application. The StimLase 2000 product is equivalent to the predicate device products in key areas of performance that affect safety and effectiveness.



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

LaserStim, Incorporated
% FDC Services, LLC
Mr. David C. Furr
Application Correspondent
8708 Capehart Cove
Austin, Texas, 78733

July 3, 2013

Re: K123177

Trade/Device Name: StimLase 2000 System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY, GZJ
Dated: June 03, 2013
Received: June 05, 2013

Dear Mr. Furr:

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

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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 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>. 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 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 -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123177
Device Name: StimLase 2000 System

Indications for Use:

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Prescription Use X or Over-the-counter use
(per CFR 801.109)

Concurrence of CDRH

Neil R Ogden
2013.07.03 15:12:04 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123177