DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 8, 2016

Medical Lasers Manufacturer Incorporated
% Jigar Shah
MDI Consultants Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K152461
Trade/Device Name: The Time Machine Series Lasers
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: August 27, 2015
Received: August 28, 2015

Dear Jigar Shah:

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 yours,

Jennifer R. Stevenson -A

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)*
K152461

Device Name

The Time Machine Series Lasers

Indications for Use *(Describe)*

The Time Machine Series Lasers Model TTML-8102000 - 810/830 nm is intended for use in temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

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.

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Medical Lasers Manufacturer Inc.

510(k) Summary

The assigned 510(k) number is: K152461

Medical Lasers Manufacturer Inc. – The Time Machine Series Lasers

1. Date Prepared: June 01, 2016

2. Submitter's Name: MEDICAL LASERS MANUFACTURER INC.

   and Address 4400 Route 9 South, Suite 1000
   Freehold NJ 07728

3. Contact Person: Mr. Bruce Schoengood
   President
   TEL: +1- 732-786-8044
   Fax: +1-561-293-2700
   Email: Bruce@medifirstsolutions.com

4. Device Trade/Proprietary Name:

   The Time Machine Series Lasers Model TTML-8102000

   Common Name: Powered Laser Surgical Instrument

   Classification Name: Regulation Number: 21 CFR Part 890.5500
   Regulation Name: Lamp, Infrared, Therapeutic Heating
   Regulatory Class: II
   Product Code: ILY
   Classification Panel: Physical Medicine

5. Predicate Device:

   The Time Machine Series Lasers device is substantially equivalent to the Joule 810/940/980 Multi-Platform System by Sciton, Inc. (K122567).

6. Device Description

   The TTML-8102000 hand held laser device operates in continuous wave mode at a fixed frequency. The Power is operated with lithium batteries. A cap covers the laser aperture and must be removed before treatment. Activating a mechanical button powers on the unit when operating by battery power. When a mechanical switch is pressed a LCD screen illuminates. The device can be operated in either of two modes which are selected by means of a mechanical switch: (1) a timer mode where treatment time is entered by means of a mechanical switch and time is displayed on the LCD screen.

The device automatically shuts off when the set time is reached. (2) a manual mode where treatment continues until the device is manually shut off. The unit is powered down by pressing the power button (battery mode). None of these functions are controlled by software. The software controls only the timer and time display. Software is embedded into a single chip circuit which contains the CPU and memory. These chips are used in simple circuits. The device can maintain skin temperature of 40-45^{0}C for at least 10 minutes based on the study conducted on three live human subject.

7. Indications for Use:

The Time Machine Series Lasers Model TTML-8102000 - 810/830 nm is intended for use in temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

8. Comparison to the Predicate Device:

Parameters	Subject Device	Predicate Device	Substantially Equivalent (SE)
Name of the device	The Time Machine Series Lasers	Joule 810/940/980 Multiplatform System	
Indications for Use	Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.	Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.	YES
K Number	K152461	K122567	

Wavelength	810 IR/830 IR nm	810/940/980 nm	YES
Fluence	120 J/Cm^2	≤ 120 J/cm^2	YES
Pulse Duration	12.5 msec	≤ 2500 msec	YES
Spot Size	3.5 mm	0.6 mm to 7.7 cm^2	YES
Output Mode	CW	cW, Pulsed single pulse-operation mode	YES
Repetition Rate	5 HZ	5-15 HZ	YES
Laser Media	Diode-pumped solid state or Diode Laser	Fibre Optic with handpiece	NO
User Interface	Push button control or LCD color touchscreen	LCD Touchscreen	YES
Treatment Beam Activation	Tailswitch	Footswtich	NO
Skin Cooling	Air Cooling	Unknown	NO
Hand Held	YES	No	NO

Indications, characteristics, technologies and medical applications of the Time Machine Series Lasers are substantial equivalent to the predicate device. The minor differences between the subject and the predicate device do not affect the safety and effectiveness based on the data generated by performance testing identified below.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the subject device in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical, Environmental and Performance Requirements.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was Medical Lasers Manufacturer Inc.'s conclusion that testing met all relevant requirements of the FDA's November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions".

The following National and International Standards were utilized for testing the subject device:

Performance Standards:

AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC)

IEC 60601-1-2 Edition 4.0 2014-02, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC))

IEC 60601-2-22 Third Edition 2007-05 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

10. Discussion of Clinical Tests Performed:

The skin temperature study has been conducted on three live human subjects to show that the skin temperature was maintained within 40 – 45^0 C for at least 10 minutes.

The results confirmed that the subject device passes the clinical test and it's safe and non-harmful to the end users.

11. Conclusions:

Conclusions drawn from the performance, bench, non-clinical and clinical tests demonstrate that the subject device is as safe, effective and performs as well as the predicate device.