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 5, 2016

Led Intellectual Properties LLC
Mr. Steve Marchese
CEO
16552 Von Karman Ave
Irvine, California 92606

Re: K153399
Trade/Device Name: LightStim Professional Led Bed
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: June 14, 2016
Received: June 14, 2016

Dear Mr. Marchese:

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

Indications for Use Statement

510(k) Number (if known) K153399

Device Name *LightStim Professional LED Bed*

Indications for Use

The LightStim Professional LED Bed is an over-the-counter device intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801. 109)

510(k) Summary of Safety and Effectiveness

LED Intellectual Properties, LLC.

Device: LightStim Professional LED Bed

1. General Information

Submitter: LED Intellectual Properties, LLC
16552 Von Karman Ave. Irvine, Ca. 92606

Contact Person: Steve Marchese & Chase Marchese
Phone: Steve (949) 502-4088 Chase (714) 924-0492

Emails: Steve@lightstim.com & Chase@lightstim.com

2. Device name and code

Device Proprietary Name: LightStim Professional LED Bed

Classification Code and name: ILY – Infrared Lamp, Therapeutic Heating

3. Predicate Devices

LED Intellectual Properties LLC: Pain Therapy Light (K083580, LightStim Professional 2-Panel Light (K150098), LightStim LED Belt (K151333)

4. Device Description

The LightStim Professional LED Bed is a device that is similar in design to the bottom half of a tanning bed. It is approximately 6.5 feet in length and 3 feet wide. It has 18,240 LEDs. There is an on/off switch that turns off after 30 minutes of use, and an AC to DC power supply.

The LightStim Professional LED Bed is intended to be operated only by a person who has been personally trained by Company personnel. Each LED Bed includes a detailed Instruction Manual and includes one-on-one training and instruction by Company training staff. That training includes a thorough review of the Instruction Manual for the device and actual one-on-one training on the operation of the LED Bed with the end user.

5. Indications for Use

The LightStim Professional LED Bed is an over-the-counter device intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.

6. Substantial Equivalency

Device Technological Characteristics Comparrison Table

Characteristic	LightStim for Pain (K083580)	LightStim LED Belt (K151333)	LightStim Professional 2-Panel Light (K150098)	LightStim Professional LED Bed
Output in milliwatts	60mW cm2	60mW cm2	System #2 = 60mW cm2	60mW cm2
Treatment Time	5-30 minutes	5-30 minutes	System #2 = 5-30 minutes	5-30 minutes
Wavelengths (nm)	630nm, 660nm, 855nm, 940nm	630nm, 660nm, 855nm, 940nm	System #2 = 630nm, 660nm, 855nm, 940nm	630nm, 660nm, 855nm, 940nm Procured from the same manufacturer with the exact same specifications as all three of the
Manufacturer	LED Intellectual Properties	LED Intellectual Properties	LED Intellectual Properties	LED Intellectual Properties
Basic Safety+Performance Electronic Compatibility	IEC/EN 60601-1 IEC/EN 60601-1-2	IEC/EN 60601-1 3rd edition	IEC/EN 60601-1 3rd Edition IEC/EN 60601-1-2	IEC/EN 60601-1 3rd Edition IEC/EN 60601-1-2
Radiation Safety	IEC-62471	IEC-62471	IEC-62471	IEC-62471
FDA Clearance	OTC	OTC	OTC	OTC

The Conclusion drawn by LED intellectual Properties, LLC based on the facts estabished in the table above, is that the LightStim Professional LED Bed is substantially equivalent to the predicates devices and raises no new issues of safety or effectiveness.

7. Performance Testing

The LightStim Professional LED Bed device was tested using the same skin temperature testing as all of the predicate devices. The participants skin temperature was measured on six different locations of the body prior to using the device, then each body location was rechecked four times at 3-minute intervals and once at the end of the 30-minute test period. All of the participants skin temperature fluctuated between 40-41.3 degrees centigrade during the 30-min temperature test, which is within the FDA guidelines for the ILY category, and those readings were almost identical to the readings of the predicate devices, which used the same procedure. Temperature readings were measured using the same device that was used for the predicate devices, a “Mastercool, Infrared Laser Thermometer”.

As the same temperature testing procedure was conducted, using the same thermometer, and achieving almost identical results as all three predicate devices, the LightStim Professional LED Bed raises no new issues of safety or effectiveness.

The LightStim Professional LED Bed device results in patient contact with an electrically powered component therefore; it was tested for conformance to IEC / EN 60601-1 3rd Edition: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

The LightStim Professional LED Bed device includes an electronic component, and it was tested for conformance to IEC / EN 60601-1-2 3rd Edition Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

Therefore, taking into consideration the Table for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the LightStim Professional LED Bed raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate devices.