



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

April 9, 2015

LED Intellectual Properties LLC
Mr. Steve Marchese
Chief Executive Officer
16552 Von Karman Avenue
Irvine, California 92606

Re: K150098

Trade/Device Name: LightStim Professional 2-Panel Light
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS, ILY
Dated: January 15, 2015
Received: January 20, 2015

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" (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 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 -S

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)

K150098

Device Name

LightStim Professional 2-Panel Light

**Indications
for Use**

The LightStim Professional 2-Panel Light System has two (2) interchangeable 2-Panel LED Systems, each mounted on a hands-free, fully articulating arms:

System #1- emitting energy in the visible and IR spectrums intended for use in the treatment of full-face wrinkles.

System #2 - emitting 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 _____
(Per 21 CFR 801. 109)

OR

Over-The-Counter Use X

510(k) Summary of Safety and Effectiveness

LED Intellectual Properties, LLC.

Device: LightStim Professional 2-Panel Light System

1. General Information

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

Contact Person: Steve Marchese
Office: (949) 502-4088 Mobile: (949) 394-2427 email: steve@lightstim.com

2. Device name and code

Device Proprietary Name: LightStim Professional 2-Panel Light System

Classification Code and name: OHS – Light Based OTC Wrinkles and ILY – Therapeutic Heating

3. Predicate Devices

LED Intellectual Properties Light for Wrinkles (K092800) + LightStim for Wrinkles (K120775) + Pain Therapy Light (K083580)

4. Device Description

The LightStim Professional 2-Panel Light System is a portable device that has two (2) separate interchangeable 2-panel treatment heads, each containing 1,130 LEDs. Each treatment heads is attached to a fully retractable and articulating arm with a 42” reach. Either one of these arms can be attached to the rolling stand for use. There is an on/off switch, and an AC to DC power supply.

The LightStim 2-Panel Light System is intended to be operated only by a person who has been personally trained by Company personnel. Each device 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 device with the end user.

5. Indications for Use

The LightStim Professional 2-Panel Light System has two (2) interchangeable 2-Panel LED Systems, each mounted on a hands-free, fully articulating arms:

System #1- emitting energy in the visible and IR spectrums intended for use in the treatment of full-face wrinkles.

System #2 - emitting 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

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Not only does the LightStim Professional 2-Panel Light System have the exact same intended use as the predicate devices, moreover, the predicate devices and the LightStim Professional 2-Panel Light System are all manufactured by the same LED Intellectual Properties, LLC, and they all utilize the exact same LED parts, with the same engineering and same output.

7. Performance Testing

Our device LightStim Professional 2-Panel results in patient contact with an electrically powered component therefore; it was tested according to 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

Our device LightStim Professional 2-Panel includes an electronic component, and it was tested according to 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance.

Therefore, taking into consideration the Table for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the LightStim Professional 2-Panel Light System raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate devices.