K131461

JAN - 6 2014

510(k) Summary of Safety & Effectiveness

LED Intellectual Properties, LLC.

Device: LightStim for Acne Mini,
Model: LS4AM

1. General Information

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

Contact Person: Steve Marchese
Office: (949) 502-4088
Mobile: (865) 394-2427

Date Person: October 10, 2012

2. Names and Code

Device Name: LightStim for Acne Mini, model: LS4AM

Classification Name: Laser Instrument, Surgical Powered – General and Plastic Surgery – Class II, OLP

Although this device is not a laser and is intended for OTC use, the manufacturer thinks this is the closet applicable classification name.

3. Predicate Devices

Quasar Blue Light Therapy System (K093963), Tanda Skincare (K080591), Silkn Blue (121435)

4. Device Description

LightStim for Acne Mini, model: LS4AM is a hand-held device consisting of low intensity light emitting diodes (LED's) that provide illumination which comes in contact with the skin. The device components include LED's of 415nm, a hand piece, a printed circuit board, an on/off switch, a resistor, a receiver jack in the hand piece to plug a power supply into and a separate AC to DC (9 volt) power supply. Treatment time is recommended to be three to four minutes and is controlled by the user

5. Indications for Use / Intended Use

LightStim for Acne Mini, model: LS4AM is intended for Over-The-Counter use for the treatment of mild to moderate acne.

6. Performance Data

A usability study of this device was conducted with 40 participants. The participants ranged in age from 11 to 61. The results showed that the participants adequately decided whether or not to use the device for their level of acne, and showed that users comprehended risks, warnings, cautions, precautions, and proper use of the device, from the Instruction Manual.

Taking into consideration the table for substantial equivalence after an analysis of safety, indications, intended uses, performance, features, technological properties and methods of operations, LED Intellectual Properties, LLC believes that LightStim for Acne Mini has shown substantial equivalence to the predicate devices. Quasar Blue Light System (K093964), Tanda Skincare (K080591), Silkn Blue (121436).

Device Comparrison Table				
Characteristic	Tanda Skincare K080591	Quasar Blue Light Therapy System K093963	Silkn Blue 121435	LightStim for Acne Mini
Intended Use	Mild to moderate acne.	Mild to moderate acne.	Mild to moderate acne.	Mild to moderate acne
Indications for Use	There is no difference between the subject and the predicate device in regards to indications for use.	There is no difference between the subject and the predicate device in regards to indications for use	There is no difference between the subject and the predicate device in regards to indications for use	LightStim for Acne Mini is intended for the use to treat mild to moderate acne.
Target Population	Women and men with mild to moderate acne.	Women and men with mild to moderate acne.	Women and men with mild to moderate acne.	Women and men with mild to moderate acne.
Output in mW	50mW/cm2	50mW/cm2	50mW/cm2	50mW/cm2
Treatment Time	Treat breakout areas for 3 minutes, twice daily	3 minutes per area	3 to 4 minutes per area	3 to 4 minutes per area
Treatment Area (cm2)	27	10	7	15.5
Wavelengths (nm)	415	415	415	415
Where Used	Home	Home	Home	Home
Design	Hand-held device	Hand-held device	Hand-held device	Hand-held device
Materials	Rigid ABS	Stainless Steel	Rigid ABS	Rigid ABS
Electromagnetic Compatibility	60601-1-2	60601-1-2	60601-1-2	IEC 60601-1-2
Basic safety and essential performance	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1
Radiation	Unkown	Unkown	Unkown	IEC 62471/IEC 62471-2

The conclusion drawn by LED Intellectual Properties, LLC, based on the comparison table and testing described above, is that the LightStim for Acne Mini raises no new issues of safety and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 6, 2014

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

Re: K131461
Trade/Device Name: LightStim for Acne Mini
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: OLP
Dated: December 02, 2013
Received: December 03, 2013

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 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,

Binita S. Ashar -S

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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)	K131461
Device Name	*LightStim for Acne Mini*
Indications for Use	LightStim for Acne Mini is an over-the-counter hand-held device intended for the use in the treatment of mild to moderate acne.

Prescription Use_____ OR Over-The-Counter Use --X--

(Per 21 CFR 801. 109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
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(Division Sign-off) for BSA

Division of Surgical Devices

510(k) Number K131461