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510(k) Summary of Safety and Effectiveness

LED Intellectual Properties, LLC.

Device: LightStim for Wrinkles K120775

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information Date: March 8, 2012

Submitter:
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2. Device name and code

Device Proprietary Name: LightStim for Wrinkles
Class Name: Laser Instrument for General and Plastic Surgery
Classification Code: OHS, Class II
Indications: Light Based Over-The-Counter Wrinkle Reduction

3. Predicate Devices

LED Intellectual Properties, LLC - Light for Wrinkles (K101190)

4. Device Description

The LightStim for Wrinkles is a hand-held device with a power output of 65mW/cm2, consisting of light emitting diodes (LED's) that emit Low and Sub IR light for direct exposure to the skin. The components include an LED array of 605nm, 630nm, 660nm, and 855nm wavelength, a (non-flammable plastic) hand piece housing, a printed circuit board upon which the LED's are mounted, single non-timer on/off switch with a resistor, receiver jack in the hand piece accommodating a removable power cord and a separate AC to DC (9-volt) power supply. Treatment time is recommended to be 3 minutes and is controlled by the user.

5. Indications for Use

The LightStim for Wrinkles is an Over-The-Counter handheld device intended for the use in the treatment of full-face wrinkles.

6. Substantial Equivalency

(a) The "LightStim for Wrinkles" K120775 is a new name for the predicate device "Light for Wrinkles". Substantial Equivalency Comparison chart is attached separately.

(b) (1) A Usability Study (equivalent to the Study conducted under K101190) with the following four goals was conducted utilizing 50 participants: (1) to attract participants that represented the "intended users" of the device; (2) to determine if consumers could correctly self-select using the Packaging labeling only; (3) to test consumer knowledge of the Packaging labeling and Instruction Manual; (4) to have consumers demonstrate their ability to adhere to what they had read in the Instruction Manual and actually operate and care for the device correctly. All four goals of the Study were met, indicating that the LightStim for Wrinkles K120775 has similar consumer usability to the Light for Wrinkles K101190.

(b) (2) An 8-week Clinical Study (equivalent to the Clinical Study conducted under K101190) with 40 participants was conducted with the premise that the LightStim for Wrinkles K120775 will deliver similar results in full-face wrinkle reduction to the Light for Wrinkles K101190 that was clinically tested for periorbital wrinkle reduction. The Study utilized the Fitzpatrick Wrinkle Scale (FWS) to judge wrinkle severity on a 1 through 9 basis. The outcome of the K120775 Clinical Study was that the participant's average full-face wrinkles base line was 5.73 on the FWS and at the end of the 8-weeks of treatment the average score revealed a reduction in full-face wrinkles to 4.54 on the scale. Further reduction to 4.2 on the scale was found at the 3-month follow-up after cessation of treatment.

(b) (3) The conclusion drawn by LED Intellectual Properties LLC, based on the facts that the LightStim for Wrinkles K120775 produced similar results in the Usability Study and similar results in the Clinical Study to the Light for Wrinkles K101190 is that the LightStim for Wrinkles raises no new issues of safety and has proven efficacy in the treatment of full-face wrinkles.

6(a) Substantial Equivalence Comparision

Characteristic	Light for Wrinkles K101190	LightStim for Wrinkles K120775
Intended Use	The Light for Wrinkles is an Over-The-Counter handheld device intended for the use in treatment of periorbital wrinkles.	The Light for Wrinkles is an Over-The-Counter hand-held device intended for the use in treatment of full-face wrinkles.
Indications for Use	Periorbital Wrinkles	Full-Face Wrinkles
Target Population	Women and men with periorbital wrinkles	Women and men with full-face wrinkles
Anatomical Sites	Periorbital Area	Entire Face
Where Used	Home	Home
Energy Used and/or Delivered	9-volt DC power transformer/approx. 65mW/cm2	9-volt DC power transformer/approx. 65mW/cm2
Human factors	Usability Study with Labeling Comprehension and self-selection conducted, with both exhibiting results of effectiveness and safety.	Usability Study with Labeling Comprehension and self-selection conducted, with both exhibiting results of effectiveness and safety
Design	Hand-held device	Hand-held device
Performance	Clinical Study of 100% of the 44 participants exibiting a reduction in fine lines and wrinkles in the periorbital area. Power is approximately 65mw/cm2.	Clinical Study of 100% of the 40 participants exibiting a reduction in facial wrinkles in the periorbital area. Power is approximately 65mw/cm2.
Standards Met	IEC-60601-1-2, IEC-60601-1, ISO-10993, ISO-13485	IEC-60601-1-2, IEC-60601-1, ISO-10993, ISO-13485
Materials	glass polymer, plastic, metal	glass plymer, plastic, metal
	glass polymer and plastic	glass polymer, ABS Lustran 348 plastic
Compatability with the Environment and Other Devices	IEC-60601-1-2	IEC-60601-1-2
Electrical Safety	Power Supply delivering a safe 9 volts DC to the hand-held device. IEC-60601-1-2, and IEC-60601-1	Power Supply delivering a safe 9-volts DC to the hand-held device. IEC-60601-1-2, and IEC-60601-1
Mechanical Safety	IEC-60601-1	IEC-60601-1
Thermal Safety	IEC-62471	IEC-62471
Radiation Safety	IEC-62471	IEC-62471

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

Re: K120775
Trade/Device Name: LightSlim for Wrinkles
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: May 11, 2012
Received: May 22, 2012

Dear Mr. Steve 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.

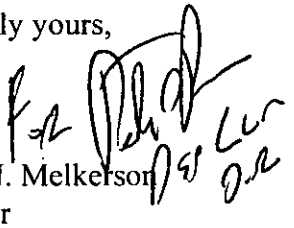
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

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Indications for Use Statement

510(k) Number (if known) K120775

Device Name *LightStim for Wrinkles*

Indications for Use The LightStim for Wrinkles is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles

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)

RPOgden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120775