510 (k) SUMMARY K101190

LED Intellectual Properties, LLC.

Device: Light for Wrinkles

JUL -1 2010

1. General Information Date Updated: June 7, 2010

Submitter: AEGIS Regulatory, Inc.
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Knoxville, TN 37922
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On Behalf of: LED Intellectual Properties, LLC
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Costa Mesa, Ca. 92626
Tel.: (949) 394-2427
Contact: Steve Marchese
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2. Names and Code

Device Proprietary Name: Light 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 – Anti-Wrinkle Light, Model AAL

4. Device Description

The Light for Wrinkles is a hand-held device with a power output of 65mW/cm2, consisting of low intensity light emitting diodes (LED's) that emit Low and Sub-IR light for direct exposure to the skin. The device components include an LED array of 605nm, 630nm, 660nm, and 855nm wavelengths, 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 5-ohm 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. Substantial Equivalency

The Light for Wrinkles has the exact same technological characteristics including design, materials, power output (65nM/cm2), the exact same wavelengths, delivery system and power transformer as the LED Intellectual Properties, LLC – Anti-Wrinkle Light, Model AAL predicate.

6. Biocompatibility

The sections of the device that come in contact with the user are the HIPS plastic handle and glass polymer LED's, which are non-sterile and are the same materials as employed on predicate devices.

7. Indications for Use / Intended Use

The Light for Wrinkles is an Over-The-Counter handheld device intended for use in the treatment of periorbital wrinkles.

6. Performance Data

Taking into consideration the statement in"5. Substantial Equivalency" above, after an analysis of the safety, indications and intended uses, performance, features, technological properties and methods of operation, LED Intellectual Properties, LLC believes that no significant differences exist between the Light for Wrinkles and the predicate device listed in Section 3, above.

We request substantially equivalency and OTC variance.

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

JUL - 1 2010

LED Intellectual Properties, LLC
% AEGIS Regulatory, Inc.
Mr. Robert T. Wagner
31 Anthem View Lane
Knoxville, Tennessee 37922

Re: K101190
Trade/Device Name: Light for Wrinkles
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
Dated: June 07, 2010
Received: June 15, 2010

Dear Mr. Wagner:

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.

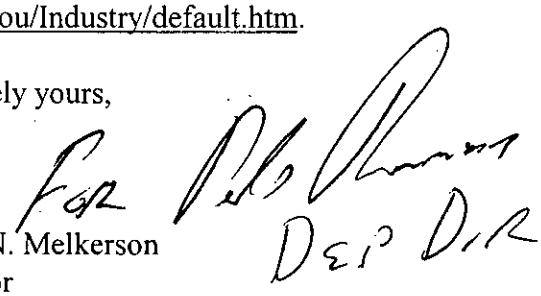
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Indications for Use

510(k) Number: K101190

Device Name: Light for Wrinkles

Indications For Use:

The Light for Winkles is an Over-The-Counter handheld device intended for use in the treatment of periorbital wrinkles.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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