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

August 7, 2017

LED Technologies, Inc.
Jelena Barbaric
Compliance Manager
6000 Greenwood Plaza Blvd., Suite 110
Greenwood Village, Colorado 80111

Re: K171386
Trade/Device Name: dpl SpectraLite
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: May 12, 2017
Received: June 5, 2017

Dear Jelena Barbaric:

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,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171386

Device Name
dpl® SpectraLite

Indications for Use *(Describe)*
The dpl® SpectraLite is an Over-the-Counter (OTC) device intended for use in treating wrinkles within periorbital region.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) Summary

Submission Date: July 4, 2017

1. Submitter Information:

LED Technologies, Inc. – Jelena Barbaric

6000 Greenwood Plaza Blvd., Suite 110

Greenwood Village, CO 80111

Tel: 303-407-6882

Email: jbarbaric@ledtechnologies.com

For Specification Developer:

LED Technologies, Inc.

Attn: Lloyd Nelson

6000 Greenwood Plaza Blvd., Suite 110

Greenwood Village, CO, 80111

Tel.: 303-407-6884

Email: lnelson@ledtechnologies.com

2. General Information

2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction

2.2 Common/usual name: dpl® SpectraLite

2.3 Proprietary Names: dpl® SpectraLite

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code OHS

2.7 Regulation Medical Specialty: General & Plastic Surgery

2.8 Review Panel: Office of Device Evaluation (ODE)
Division of Surgical Devices (DSD)
General Surgery Device Branch One – Light Based/Laser (GSDB1)

3. Device Description

The dpl® SpectraLite system is an over-the counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles within the periorbital region. The

device uses four types of LEDs: 605nm amber, 625nm red, 660nm red, and 880nm infrared. The treatment time is controlled by the user. There are no user settings or adjustments required.

The dpl® SpectraLite system components include the device containing the LED module, USB charging cord, and a storage case.

The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components. The device is sold as Ove The Counter (OTC).

4. Indications/Intended Use:

The dpl® SpectraLite is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

Rx or OTC:

> The dpl® SpectraLite is an Over-the Counter device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are design for layman understanding and use. The predicate device is OTC.

5. Predicate Device:

This device is substantially equivalent to the following predicate, which is currently in safe and effective commerce under product code OHS:

K141181 – dpl® Nuve for Wrinkles (LED Technologies, Inc.)

Predicate Chart

Device	dpl® SpectraLite LED Technologies, Inc. KXXXXXX This Submission	dpl® Nüve for Wrinkles LED Technologies, Inc. K141181 A Predicate Device
Indications	The dpl® SpectraLite is an Over-the-Counter (OTC) device intended for the use in treating wrinkles within periorbital region.	The dpl® Nüve for Wrinkles is an Over-the-Counter (OTC) device intended for the use in treating full-face wrinkles.
Wavelengths	605 nm, 625 nm, 660nm, 880 nm	605 nm, 625 nm, 660nm, 880 nm
Modes	On/Off	On/Off

Irradiance Source	LED	LED
Visible light LEDs	Yes	Yes
Treatment Area	28 cm^2	30 cm^2
Energy Level	61.59 mW/cm^2	62.07 mW/cm^2
Power Supply	120-240V 5VDC Power Adapter	120-240V AC Power Adapter
Treatment Time	3 minutes per treatment	3 minutes per treatment
Target Population	Individuals with wrinkles on their face within the periorbital region.	Individuals with wrinkles on their face.
Location for Use	OTC	OTC

Summary of the technological characteristics of the device compared to predicate device:

1. Has the same intended use as the predicate device (I.e., treatment of wrinkles);
2. Has the same/similar output (i.e., 62 mW/cm^2) as the predicate device;
3. Utilizes the same number of wavelengths (i.e., 4 wavelengths between 605 nm – 880 nm) as the predicate device;
4. Utilizes the same treatment duration (i.e., 180 seconds) as the predicate device;
5. Utilizes the same treatment regimen of five days a week for eight weeks.

The dpl® SpectraLite system and the above referenced predicate device are Over the Counter Devices used to treat wrinkles as defined in 21 CFR § 878.4810. These devices utilize red and IR diodes between 605 nm to 880 nm to provide narrow bands of light energy to treat wrinkles. The performance achieved by these devices is similar with equal power output. Based upon comparison to the predicate devices, the dpl® SpectraLite has the same intended uses, with similar technological characteristics as the predicate device.

The devices are intended to be placed directly on the skin. The materials used for the device are similar to what is used in the dpl® Nüve, with the addition of the TPE Silicone for user comfort. No new biocompatibility issues are introduced with the addition of TPE Silicone.

The dpl® SpectraLite is battery powered (LI-Ion Battery 5V USB & 3.7 V Battery). Battery is charged via Universal USB charger cord. The change in energy (the addition of battery) is usually part of a redesign to provide a portable version of a predicate device. The indication for use does not change and is not expanded. Operation of device does not change. The system performs as intended and does not raise any new safety or effectiveness issues.

6. Performance Testing and Standards:

Testing of the dpl® SpectraLite system, included functional performance testing, software validation testing, and user safety testing.

Safety and functionality testing demonstrates that the dpl® SpectraLite system conforms to various international consensus standards.

IEC 60601-1: (2012) Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 62471: (2006): Photobiological safety of lamps and lamp systems.

IEC 60601-1-2 (2014): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Compatibility.

Additional Tests for CE Medical Certification

IEC 61000-3-2: (2014): Electromagnetic Compatibility (EMC) – Part 3-2: Limits – Limits for Harmonic Current Emissions (Equipment Input Current ≤ 16 A Per Phase).

IEC 61000-3-3: (2013): Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection.

EC 1907/2006 - Registration, Evaluation, Authorization and Restriction of Chemicals – REACH

IEC 62321:2008 Ed. 1.0 - Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers).

IEC 62321 -4: 2013 – Determination of certain substances in electrotechnical products – Part 4: Mercuryin polymers, metals and electronics by CV-AAS, CV-AFS, ICP-OES and ICP-MS.

IEC 62321 -5:2013 - Determination of certain substances in electrotechnical products - Part 5: Cadmium, lead and chromium in polymers and electronics and cadmium and lead in metals by AAS, AFS, ICP-OES and ICP-MS.

IEC 62321-6:2015 - Determination of certain substances in electrotechnical products - Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography - mass spectrometry (GC-MS).

IEC 62321-8 CVD – Determination of certain substances in electrotechnical products – Part 8: Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolizer/thermal desorption accessory (Py-TD-GC-MS).

UN 38.3 Battery Certification.

Additional FCC Testing Performed for Retail Request

FCC 47 CFR Part 15 Subpart B – Radio frequency devices.

Biocompatibility

US FDA 21 CFR 177.1810: Styrene block polymers – TPE Test

The dpl® SpectraLite system software was tested and validated in accordance with FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices".

A Usability Study was conducted with 15 participants.

The results of the study found that:

100% of the participants were able to demonstrate the light sensitivity test.

100% of the participants were able to use the device successfully.

The conclusions drawn from nonclinical tests demonstrate that the device is safe, as effective, and performs as well as the legally marketed devices.

7. Statement of Safety Effectiveness:

The information in this 510 (k) submission was used to support the safety and effectiveness of this device with respect to its cited properties.

8. Summary

After analysis of safety, indications, intended uses, dose rates, performance, features, design materials, power output, technological properties, treatment areas, treatment regimens and methods of operation, the manufacturer asserts that no significant differences exist between the subject device and predicate, and no different questions of safety and effectiveness arise. Therefore, the subject device is substantial equivalence to the predicate.