July 20, 2018

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

Re: K180320
Trade/Device Name: dpl IIa Panel
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, OHS
Dated: February 2, 2018
Received: February 5, 2018

Dear Jelena Barbaric:

This is a corrected letter of the original one dated on April 3, 2018. In the original letter, the Product Code is OLP. In this corrected letter, the Product Code is OLP, OHS.

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K180320

Device Name
dpl® IIa Panel

Indications for Use *(Describe)*
The dpl® IIa Panel is an Over-the Counter (OTC) device intended for use in treating wrinkles, and treatment of mild to moderate inflammatory acne.

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.

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510 (k) Summary

This summary of 510 (k) information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: February 2nd, 2018

1. **Submitter Information:** LED Technologies, Inc. – Jelena Barbaric

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   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.: 303-646-0543. Ext 117

   Email: lnelson@ledtechnologies.com

2. General Information

2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction/Over-The-Counter Light Based Laser for Acne

2.2 Common/usual name: dpl® IIa Panel

2.3 Proprietary Names: dpl® IIa Panel

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code OHS/OLP

2.7 Review Panel: General & Plastic Surgery

3. Device Description

The dpl® IIa Panel system is an over-the counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles and mild to moderate

inflammatory acne. The device uses five types of LEDs: 605nm amber, 630nm red, 660nm red, and 880nm infrared, and 415nm blue. The treatment time is controlled by the user. There are no user settings or adjustments required.

The dpl® IIa Panel system components include the panel unit containing the LED module, power supply, goggles, and 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 Over the Counter (OTC).

4. Indications/Intended Use:

The dpl® IIa Panel is an Over-the-Counter (OTC) device intended for use in treating wrinkles, and treatment of mild to moderate inflammatory acne.

5. Predicate Device:

This device is substantially equivalent to the following predicates, which are currently in safe and effective commerce under product codes OHS/OLP:

K171390 – dpl® II Panel (LED Technologies, Inc.)
K124042 – Tanda Mini (Tanda)
K121435 – Silkin Blue (Silkin)
K160691 – Acne Light Therapy Wand (Zuco, Inc.)

Comparison Chart

Device	dpl® IIa Panel LED Technologies, Inc. KXXXXXX	dpl® II Panel LED Technologies, Inc. K171390	Tanda Mini K124042	Silkin Blue K121435	Acne Light Therapy Wand K160691
Wavelengths	605nm, 630nm, 660nm, 880nm 415nm	605nm, 630nm, 660nm, 880nm	414nm	415nm	442nm 633nm
Irradiance source	LED	LED	LED	LED	LED
Treatment Area	415 cm^2	415 cm^2	3.37 cm^2	7 cm^2	1.594 cm^2
Treatment Time	3 minutes per treatment daily	3 minutes per treatment daily	90 seconds treatment, two times daily	3-4 minutes per treatment	2 minutes per treatment, 3 X per day
Type/Class	OTC	OTC	OTC	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/acne);
2. Has the same/similar output (mW/cm^2) as predicate devices;
3. Utilizes the similar treatment duration (i.e., 180 seconds) as the predicate devices;

The dpl® IIa Panel system and the above referenced predicate devices are Over the Counter Devices used to treat wrinkles and acne 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, and red 630 nm and blue 415 nm diodes for treatment of mild to moderate inflammatory acne. The performance achieved by these devices is similar with equal/similar power output. The devices are intended to be placed directly on the skin. They are manufactured out of similar materials. Based upon comparison to the predicate devices, the dpl® IIa Panel system has the same intended uses, with similar technological characteristics as predicate devices. The system performs as intended and does not raise any new safety or effectiveness issues.

4. **Performance Testing and Standards:**

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

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

AAMI/ANSI/ES 60601-1: (2012): medical Electrical Equipment part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2 Edition 4 (2014-02): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Compatibility.

ISO 10993-10:2010 Biological evaluation of medical devices part 10: Tests for irritation and delayed-type hypersensitivity.

The dpl® IIa Panel 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 16 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 substantially equivalent to the legally marketed predicate devices.

5. Conclusion

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.