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

March 14, 2019

Re: K183247
Trade/Device Name: dpl® Faceware
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, OLP
Dated: February 15, 2019
Received: February 15, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.03.14 14:26:04 -04'00'

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)*
K183247

Device Name
dpl® Faceware

Indications for Use *(Describe)*
The dpl® Faceware is an Over-the-Counter (OTC) device intended for treatment of wrinkles and 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.

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

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510 (k) Summary

This summary of 510 (k) information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Submission Date: November 19th, 2018

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.: 303-646-0543. 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® Faceware

2.3 Proprietary Names: dpl® Faceware

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® Faceware 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, 880nm infrared, and 415 blue.

The dpl® Faceware components include the device containing the LED module, USB power cord, and power adapter.

The treatment time is controlled by the user. There are no user settings or adjustments required.

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.

Indications/Intended Use:

The dpl® Faceware is an Over-the-Counter (OTC) LED device intended for use in treating wrinkles and mild to moderate inflammatory acne.

4. Predicate Devices:

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

K180320 – dpl® IIa Panel (LED Technologies, Inc.)
K180447 – reVive Light Therapy® LED Cleansing System (LED Technologies, Inc.)
K171386 – dpl® SpectraLite (LED Technologies, Inc.)

Comparison Chart

Device	**dpl® Faceware** KXXXXXX	**dpl® IIa Panel** LED Technologies, Inc. K180320	**reVive Light Therapy® LED Cleansing System** LED Technologies, Inc. K180447	**dpl® SpectraLite** LED Technologies, Inc. K171386
Wavelengths	605nm, 630nm, 660nm, 880nm, 415nm	605nm, 630nm, 660nm, 880nm, 415nm	630nm, 415nm	605nm, 630nm, 660nm, 880nm
Irradiance source	LED	LED	LED	LED
Treatment Area (cm^2)	81 (acne) 135.8 (wrinkle)	415	18.86	28
Treatment Time	3 minutes per treatment	3 minutes per treatment	3 minutes per treatment	3 minutes per treatment
Type/Class	OTC	OTC	OTC	OTC

IFU	For treatment of wrinkles and mild to moderate inflammatory acne	For treatment of wrinkles and mild to moderate inflammatory acne	For treatment of mild to moderate inflammatory acne	For treatment of periorbital wrinkles

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

1. Has the same/similar intended use as the predicate devices (I.e., treatment of wrinkles/mild to moderate inflammatory acne);
2. Has the similar output (mW/cm^2) as predicate devices;
3. Utilizes the same/similar treatment duration as the predicate devices;
4. Utilizes the similar recommended treatment regimen.

The dpl® Faceware 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 and blue LED diodes to treat mild to moderate inflammatory acne. The performance achieved by these devices is same/similar with similar power output.

The dpl® Faceware is battery powered (LI-Ion Battery 5V USB & 3.7 V Battery). Battery is charged via Universal USB charger cord and is equivalent to the battery used in predicate device dpl® SpectraLite.

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® Faceware 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.

5. **Performance Testing and Standards:**

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

Safety and functionality testing demonstrate that the dpl® Faceware conforms to various international consensus standards.

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

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

Biocompatibility

ISO 10993-5:2009 – Cytotoxicity Test
ISO 10993-10:2010 – Intracutaneous reactivity test
ISO 10993-10:2010 – Skin Sensitization Test

The dpl® Faceware 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.

6. 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.

7. 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.