December 21, 2021

LED Technologies, Inc.
Jelena Barbaric
Compliance Manager
12821 Starkey Rd., Suite 4900
Largo, Florida 33773

Re: K210968
Trade/Device Name: reVive Light Therapy Essentials
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
Dated: November 24, 2021
Received: November 29, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya, D.Eng.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210968

Device Name
reVive Light Therapy® Essentials

Indications for Use *(Describe)*
The reVive Light Therapy® Essentials is an Over the Counter (OTC) device intended for 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 – K210968

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

Submission Date: December 16th, 2021

1. **Submitter Information:**

LED Technologies, Inc. – Jelena Barbaric

12821 Starkey Rd., Suite 4900

Largo, FL 33773

Tel: 727-285-8300 Ext 203

Email: jbarbaric@ledtechnologies.com

For Specification Developer:

LED Technologies, Inc.

Attn: Lloyd Nelson

12821 Starkey Rd., Suite 4900

Largo, FL 33773

Tel.: 727-285-8300. Ext 201

Email: lnelson@ledtechnologies.com

2. General Information

2.1 Classification Name: Over the Counter Powered Light Based Laser for Acne

2.2 Common/usual name: reVive Light Therapy® Essentials

2.3 Proprietary Names: reVive Light Therapy® Essentials

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OLP

2.7 Review Panel: General & Plastic Surgery

3. Device Description

The reVive Light Therapy® Essentials is an over-the counter light emitting diode (LED) device, that emits energy for use in dermatology for the treatment of mild to moderate inflammatory acne. The device uses two types of LEDs: 630nm red and 415nm blue.

The reVive Light Therapy® Essentials components include the device containing the LED module.

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 reVive Light Therapy® Essentials is an Over the Counter (OTC) LED device intended for use in treating mild to moderate inflammatory acne.

4. Predicate Devices:

Primary Predicate - **K180447 – reVive Light Therapy® LED Cleansing System (LED Technologies, Inc.)**

K180320 – dpl® IIa Panel (LED Technologies, Inc.)

Comparison Chart

Device	**reVive Light Therapy® Essentials** K210968	**dpl® IIa Panel** LED Technologies, Inc. K180320	**Primary Predicate reVive Light Therapy® LED Cleansing System** LED Technologies, Inc. K180447
Wavelengths	630nm, 415nm	605nm, 630nm, 660nm, 880nm 415nm	630nm, 415nm
Irradiance source	LED	LED	LED
Treatment Area (cm^2)	7	415	18.86
Treatment Time	3 minutes per treatment	3 minutes per treatment	3 minutes per treatment
Type/Class	OTC	OTC	OTC
IFU	For treatment of mild to moderate inflammatory acne	For treatment of wrinkles & mild to moderate inflammatory acne	For treatment of mild to moderate inflammatory acne

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

1. Has the same intended use as the predicate devices (i.e., treatment of mild to moderate inflammatory acne).
2. Has similar technical characteristics.

   The device has same control mechanism, same operating principle, and energy type. It uses the same method of operation as described in K180447 and K180320.

   The subject device is smaller in size. The changes do not have significant effect on the use of the device. The risk assessment did not identify any new or significantly modified risks. Moreover, there were no unexpected issues from validation and verification activities.

   Therefore, the minor changes in the device appearance do not affect the substantial equivalence of the subject device with the predicates.
3. Has the same method of operation.
4. Utilizes the same treatment duration as the predicate devices.

The reVive Light Therapy® Essentials and the above referenced predicate devices are Over the Counter Devices used to treat mild to moderate inflammatory acne as defined in 21 CFR § 878.4810. These devices utilize red and blue diodes with 630 nm and 415 nm to provide narrow bands of light energy to treat acne. The performance achieved by these devices is same with similar power output.

The reVive Light Therapy® Essentials is powered by Battery (3 AA Batteries) or via Universal USB power source.

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 reVive Light Therapy® Essentials 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 reVive Light Therapy® Essentials, included functional performance testing, software validation, testing, and user safety testing.

   Safety and functionality testing demonstrate that the reVive Light Therapy® Essentials conforms to various international consensus standards.

   ANSI/AAMI ES 60601-1:2005® + 2012 and A1:2012 IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012: Medical Electrical Equipment part 1: General Requirements for Basic Safety and Essential Performance.

   ANSI/AAMI/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
ISO 10993-11:2017 – Acute Systemic Toxicity
USP General Chapter 151 – Material Medicated Pyrogenicity

Additionally, the subject device tissue contacting components are the ABS plastic and the PC. The materials data from previous submissions is identical in materials selection, manufacturing process, chemical composition of the materials, as well as nature of patient contact, proving the ABS and PC of the reVive Light Therapy® Essentials medical device in its final finished form is identical to the ABS and PC material of the predicate devices.

The reVive Light Therapy® Essentials 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 correct preparation of device for use.

100% of the participants were able to demonstrate correct device usage.

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

6. 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.