July 27, 2022

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

Re: K221430
Trade/Device Name: reVive Light Therapy LED Cleansing System
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: July 13, 2022
Received: July 15, 2022

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 801and Part 809); 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,

Jianting Wang
Acting 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)*
K221430

Device Name
reVive Light Therapy® LED Cleansing System

Indications for Use *(Describe)*
The reVive Light Therapy LED Cleansing System is 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 K221430

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

Submission Date: May 17th, 2022

1. **Submitter Information:**

LED Technologies, Inc. – Jelena Barbaric

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Largo, FL 33773

Tel: 303-845-0028

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For Specification Developer:

LED Technologies, Inc.

Attn: Lloyd Nelson

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Largo, FL 33773

Tel.: 303-748-0545

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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: reVive Light Therapy® LED Cleansing System

2.3 Proprietary Names: reVive Light Therapy® LED Cleansing System

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 reVive Light Therapy® LED Cleansing 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, as defined in 21 CFR § 878.4810.

In addition to the LED light therapy treatment function, reVive Light Therapy® LED Cleansing System has a separate function for cleansing. The system includes two cleansing brush-heads, constructed of TPE material.

The reVive Light Therapy® LED Cleansing System components include the device containing the LED module, USB power cord, and power adapter.

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 reVive Light Therapy® LED Cleansing System is intended for treatment of wrinkles and 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:

K180445 – The reVive Light Therapy® LED Cleansing System (LED Technologies, Inc.)

K180447 – The reVive Light Therapy® LED Cleansing System (LED Technologies, Inc.)

Comparison Chart

	New Device K221430	**Predicate Device K180445**	**Predicate Device K180447**
Wavelengths	Wrinkle Treatment: 605nm 630nm 660nm 880nm Acne Treatment: 415nm 630nm	 605nm 630nm 660nm 880nm	 415nm 630nm
Irradiance Source	LED	LED	LED
Treatment Area	18.86 cm^2	18.86 cm^2	18.86 cm^2
Treatment Method	Place device directly on the skin	Place device directly on the skin	Place device directly on the skin
Treatment Time	3 minutes	3 minutes	3 minutes

Material	ABS	ABS	ABS
Power Source	3.7 V Lithium Battery	3.7 V Lithium Battery	3.7 V Lithium Battery
Type/Class	OTC	OTC	OTC
IFU	Treatment of wrinkles and mild to moderate inflammatory acne	Treatment of wrinkles	Treatment of mild to moderate inflammatory acne

6. Testing

The reVive Light Therapy® LED Cleansing system software was tested and validated in accordance with FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices".

The Testing confirmed that modifications made to the device were correctly implemented and that the device performs as well as the legally marketed devices.

7. Conclusion

In sum, the only modification introduced is the updated software and associated hardware. All other features including the technological characteristics, material, treatment method, treatment time, and the intended uses of a new device are identical to that of the cleared devices. The introduced modification does not present changes to the fundamental scientific technology and essential parameters of the originally cleared predicate devices.

Testing confirmed that the performance of the reVive Light Therapy® LED Cleansing System meets the product system requirements, which is based on the predicate devices. Therefore, the modification resulted in a device that performs the same as the predicate devices.