



June 4, 2018

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

Re: K180447

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: OLP
Dated: February 16, 2018
Received: February 20, 2018

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.

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,

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

Indications for Use

510(k) Number (if known)
K180447

Device Name
reVive Light Therapy® LED Cleansing System

Indications for Use (Describe)
reVive Light Therapy® LED Cleansing System is an Over-the-Counter (OTC) LED device intended for use in treating 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

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

Preparation Date: June 1st, 2018

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

- 2.1 Classification Name: Over-The- Counter Light Based Laser for Acne
- 2.2 Common/usual device 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 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 mild to moderate inflammatory acne. The device uses two types of LEDs: 630nm red and 415nm

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

The reVive Light Therapy® LED Cleansing System components include the unit 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). It is intended for users 13 years or older.

4. Indications/Intended Use:

The reVive Light Therapy® LED Cleansing System is an Over-the-Counter (OTC) device intended for use in 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 OLP:

Primary predicate:

K153081 – Clear Bi-Light (Michael Todd)

Reference predicates:

K081307 – OmniLux Clear U

K170260 – BC-001 + Acne Purifier

K132383 – Nutra Light Blue

K160691 – Acne Light Therapy Wand

Device	reVive Light Therapy® LED Cleansing System K180447	Clear Bi-Light K153081	OmniLux Clear U K081307	BC-001 + Acne Purifier K170260	Nutra Light Blue K132383	Acne Light Therapy Wand K160691
Wavelengths	415nm, 630nm	405-420nm 630-660nm	415nm, 633nm	415nm 660nm	410nm	442nm 630nm
Irradiance source	LED	LED	LED	LED	LED	LED
Treatment Area	18.86 cm ²	20 cm ²	28.7 cm ²	9.1	31.6	1.594
Treatment Time	3 minutes per treatment	3 minutes per treatment	20 minutes per treatment	1.5 minutes per area	3 minutes treatment	3 minutes per treatment

Type/Class	OTC	OTC	OTC	OTC	OTC	OTC
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Predicate Chart

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 mild to moderate inflammatory acne);
2. Has the similar output (mW/cm²) as predicate devices;
3. Utilizes the same/similar treatment duration as the predicate devices;
4. Utilizes the similar recommended treatment regimen.

The reVive Light Therapy® LED Cleansing System and the above referenced predicate devices are Over the Counter Devices used to treat acne as defined in 21 CFR § 878.4810. These devices utilize red and blue diodes at 630 and 415 nm for treatment of mild to moderate inflammatory acne. The performance achieved by these devices is comparable with 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 reVive Light Therapy® LED Cleansing 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.

5. Performance Testing and Standards:

Testing of the reVive Light Therapy® LED Cleansing System, included functional performance testing, software validation, testing, and user safety testing.

Safety and functionality testing demonstrates that the reVive Light Therapy® LED Cleansing System conforms to various international consensus standards.

IEC 60601-1: (2006): medical Electrical Equipment part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2 (2007): 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 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".

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.

Self-Selection Study

The self-selection study was not conducted, as the box labeling was comparable to that of primary predicate.

Thermal Performance Testing

The performance testing was conducted measuring the temperature during the common use of the device. The test results demonstrated that the temperature of the device does not exceed 41C, even after the continuous use for 30 minutes, 10 times longer than the recommended treatment time of 3 minutes.

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.