May 1, 2020

Beijing ADSS Development Co., Ltd.
℅ Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401 China

Re: K192295
Trade/Device Name: LED Therapy Device
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: March 6, 2020
Received: March 9, 2020

Dear Ray Wang:

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,

Colin Kejing Chen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192295

Device Name
LED Therapy Device

Indications for Use *(Describe)*
The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.
The device is indicated for adults only.

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.

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192295

1. Date of Preparation

   04/30/2020

2. Sponsor

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: LED THERAPY DEVICE
Model(s): LED THERAPY DEVICE

Regulatory Information:
Classification Name: Light Based Over-The-Counter Powered Light Based Laser For Acne/Light Based over the Counter Wrinkle Reduction
Classification: 2;
Product Code: OLP/OHS;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Intended Use Statement:
The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.
The device is indicated for adults only.

5. Device Description

The LED THERAPY DEVICE is a facemask-shaped device, which directly applies light onto the face skin surface and makes use of specific light spectral characteristics.
The proposed device has total of 150 LEDs and operates in two modes. One mode emits blue light with wavelengths centered at 415nm ±5nm, and the other mode emits red light with wavelengths centered at 630nm ±5nm.
The red light is intended for the treatment of wrinkles. The blue light is intended for the treatment of the mild to moderate inflammatory acne.
The blue light mode has ten level energy output settings, 5mw/cm2-50mw/cm2. The red light mode has ten level energy output settings, 8mw/cm2-80mw/cm2.
The user can change the treatment mode according to their own needs. The LED THERAPY DEVICE is powered via a plug-in power adapter.

6. Identification of Predicate Device

Primary Predicate Device #1:
510(k) Number: K162098
Product Name: LED Phototherapy Device
Manufacturer: Li-Tek Electronic Technology Corporation

Predicate Device #2:
510(k) Number: K172555
Product Name: Sapphire, Elevare Sapphire
Manufacturer: Omm Imports, Inc. d/b/a Zero Gravity

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device conforms to the following standards:

No.	Standard Title	Year	Recognition Number
01	ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	2-245
02	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	2-174
03	ANSI AAMI ES60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012	19-4
04	IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	2014	19-8
05	IEC 60601-1-11, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2015	19-14
06	IEC 62471, Photobiological safety of lamps and lamp systems	2006	12-249
07	IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices	2015	5-114

8. Usability Study Summary

A Self-Selection, Labeling Comprehension, and Usability Study has been conducted for the LED THERAPY DEVICE.

The study was carried out from 2/17/2020 through 3/1/2020, at the AD Precision Health storefront and office, 2810 E Trinity Mills Rd #130, Carrollton TX 75006, America.

45 end-users enrolled for the study, which included 15 participants with mild inflammatory acne, 15 participants with moderate inflammatory acne, and 15 participants with periorbital wrinkles.

Results of Usability Study Questionnaire

The results from the questionnaire portion indicated an overall subject score of 100% in understanding of our device, with 100% of each question relating to Risks, Warnings, Cautions, Precautions and a variety of other important data from the Instruction Manual, being correctly answered. The results of this cohort found that an overall subject score of 100% was achieved, with 100% of each question correctly answered, thus reaching the goal of the question score ≥95% and the participant overall score ≥95%.

Results of Operation demonstration of the device

The results of this cohort found that 100% of the participants were able to:

－Correctly demonstrate how to install the device, perform the Light Sensitivity Test, operate the device, and clean & disinfect the device.

The results of this cohort found that an overall subject score of 100% was achieved, thus reaching the goal of Target Levels: Participant Overall score ≥95%.

Conclusion:

According to the results of study, all participants who represented the intended user population of the LED THERAPY DEVICE, understood how to decide whether or not they should use the device, understood the instruction for use, and could operate the device successfully.

9. Clinical Test Conclusion

No Clinical Test conducted.

10. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Primary Predicate Device #1 K162098	Predicate Device #2 K172555	Remark
Product Code	OLP, OHS	OLP, OHS	OLP	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	Class 2	Class 2	Class 2	SAME
Intended Use	The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne. The device is indicated for adults only.	The red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	The SAPPHIRE is an over –the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use in the treatment of mild to moderate inflammatory acne.	SAME
Prescription/ OTC	OTC	OTC	OTC	SAME

Table 2 Performance Comparison

ITEM	Proposed Device	Primary Predicate Device #1 K162098	Predicate Device #2 K172555	Remark
Power Source	5.V DC 2.0 A Powered by direct plug-in adapter: Input 100-240V AC, 50/60 Hz, 0.5A Max., Output 5.0V DC 2.0A	3.7V 1050mAh Li battery	Not Available	Difference Analysis as below the table
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	SAME
Power (mW/cm^2)	Red light: 80±10% Blue light: 50±10%	Red light: 80±10% Blue light: 65±10%	Blue light: 50	SAME
Wavelength	Blue light: 415nm±5nm Red light: 630nm±5nm	Blue light: 415nm±3nm Red light: 630nm±3nm	Blue light: 415nm±5nm	SAME
Handheld	Yes	Yes	Yes	SAME
Treatment Duration	3-5 minutes each time, twice a week	3 minutes per target area; 2 treatments per week for 6 weeks	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)	SAME
Main Materials	PC+ABS	ABS plastic	Not Available	Difference Analysis

				as below the table

Table 3 Safety Comparison

ITEM	Proposed Device	Primary Predicate Device #1 K162098	Predicate Device #2 K172555	Remark
Electrical Safety	Comply with IEC 60601-1, IEC 60601-1-11	Comply with IEC 60601-1	Comply with IEC 60601-1, IEC 60601-1-11	SAME
Photobiological Safety	Comply with IEC 62471	Comply with IEC 62471	Comply with IEC 62471	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Biocompatibility	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	SAME
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SAME

Difference Analysis:

The subject device has indications for use, level of safety, and performance characteristics, that do not raise new types of questions regarding the safety and efficacy of the subject device.

For differences in the power sources, electrical safety testing according to IEC 60601-1 was conducted, and the test results demonstrated that the power source used in proposed device met the requirements of the standards.

For the device's user-contacting materials, biocompatibility testing according to ISO 10993 standard was conducted. The test results demonstrated that the materials used in proposed device met the requirements of the standard, and did not raise new safety or effectiveness concerns.

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate K162098.