January 26, 2022

LED Intellectual Properties LLC
Chase Marchese
VP of Manufacturing
16552 Von Karman Ave
Irvine, California 92606

Re: K212771
Trade/Device Name: LightStim Elipsa
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: December 1, 2021
Received: December 1, 2021

Dear Chase Marchese:

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 and 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,

Purva Pandya
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)*
K212771

Device Name
LightStim Elipsa

Indications for Use *(Describe)*
The LightStim Elipsa is a LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs). It is intended to emit energy in the red and infrared region of the light spectrum to provide treatment for full face wrinkles. The blue and red light spectrum is intended for the 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

LED Intellectual Properties, LLC.
Device: LightStim Elipsa
K212771

1. General Information

Submitter: LED Intellectual Properties, LLC
16552 Von Karman Ave. Irvine, Ca. 92606

Contact Person: Steve Marchese & Chase Marchese
Phone: Chase (714) 924-0492
Date Prepared: 2022/01/19
Emails: Chase@lightstim.com & Steve@lightstim.com

2. Device name and code

Device Proprietary Name: LightStim Elipsa

Product Code and name:

OHS - Light Based Over-the-Counter Wrinkle Reduction
OLP - Over-the-Counter Powered Light Based Laser For Acne

Classification Name: Laser Surgical Instrument For Use in General And Plastic Surgery And in Dermatology. 21 CFR 878.4810

Common or Usual Name: Light-Based over-the-counter wrinkle reduction and acne treatment.

Regulatory Class: II

3. Predicate Devices

SHENZHEN KAIYAN MEDICAL CO LTD, DemarkQ (K203214)
Medtek Skincare, LLC, Poly Clear (K183708)
LED Intellectual Properties, LLC, LightStim Professional 2-Panel Light (K150098)

4. Device Description

The LightStim Elipsa is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of acne and wrinkles. The device uses four types of LEDs for Wrinkles: 612nm amber, 645nm red, 655nm red, and 850nm infrared and two types of LEDs for Acne: 410nm and 645nm. The treatment time is controlled by the user. There are no user settings or adjustments required.

The LightStim Elipsa system components include the device containing the LED module, power supply, goggles, and travel case.

The LightStim Elipsa does not contain any user serviceable components. The device is sold as Over-the-counter (OTC)

5. Indications for Use

The LightStim Elipsa is a LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs. It is intended to emit energy in the red and infrared region of the light spectrum to provide treatment for full face wrinkles. The blue and red light spectrum is intended for the treatment of mild to moderate inflammatory acne.

6. Comparison of Technological Characteristics

Company	**SHENZHEN KAIYAN MEDICAL CO LTD**	**Medtek Skincare, LLC**	**LED Intellectual Properties, LLC**	**LED Intellectual Properties, LLC**
Trade Name	**DemarkQ**	**Poly Clear**	**LightStim Professional 2-Panel Light**	**LightStim Elipsa**
510(k) Number	K203214	K183708	K150098	Proposed Device
Product Code	OLP	OLP	OHS	OLP & OHS
FDA Device Classification	**Class II**	**Class II**	**Class II**	**Class II**
FDA Clearance	Over the Counter	Over the Counter	Over the Counter	Over the Counter
Indications for use	The DemarkQ is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.	The Poly Clear combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the light spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	Two (2) interchangeable 2-Panel LED Systems, each mounted on a hands-free, fully articulating arm: System #1 = intended for the use in the treatment of full-face wrinkles. System #2 = Not applicable	The LightStim Elipsa is a LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs). It is intended to emit energy in the red and infrared region of the light spectrum to provide treatment for full face wrinkles. The blue and red light spectrum is intended for the treatment of mild to moderate inflammatory acne.
Target Population	Women and Men with mild to moderate acne.	Women and Men with mild to moderate acne.	System #1 = People with full-face wrinkles. System #2 =Not applicable	People with Full-face wrinkles. Women and Men with mild to moderate inflammatory acne.
Wavelengths (nm)	630nm +/-10nm 415nm =/-10nm	633nm +/-10nm 417nm =/-10nm	System #1 = 605nm, 630nm, 660nm, 855nm, System #2 = Not applicable	RED: 612nm, 645nm, 655nm, 850nm BLUE: 410nm & 645nm
Output in milliwatts	DemarkQ WOW: Red: 5 Blue: 25 DemarkQ POP: Red: 25 Blue: 25 +/- 5	Combo Red/Blue head: Red 30mW/cm^2 +/-10nm Blue 20mW/cm^2 +/-10nm	System #1 = 65mW cm2 System #2 = Not applicable	RED: 11.8 mW/cm2 BLUE: 12.8 mW/cm2
Treatment Time	3 minutes per treatment	Blue: 13minutes. Red: 15 minutes	System #1 = 3min System #2 = Not applicable	RED: 16 minutes per area BLUE: 12 minutes per area
Dose	RED: 0.9-4.5 J/cm2 Blue: 4.5 J/cm2	Red: 52 J/cm2 Blue 26 J/cm2	System #1 = 11.7 j/cm^2 System #2 = Not applicable	RED: 11.3 j/cm^2 BLUE: 9.2 j/cm^2
Total dose/Treatment	9 J/cm2	52 J/cm2	11.7 J/cm2	Red 11.3 J/cm2 Blue 9.2 J/cm2
Total dose/week	63 J/cm2	78 J/cm2	58.5 J/cm2	Red 56.5 J/cm2 Blue 46 J/cm2

7. Performance Testing

The LightStim Elipsa device results in patient contact with an electrically powered component; therefore, it was tested for conformance to AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 4th Edition: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

The LightStim Elipsa device includes an electronic component, and it was tested for conformance to IEC 60601-1-2:2014 4th Edition Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance- Collateral standard: Electromagnetic Compatibility-Requirements and tests.

The LightStim Elipsa device was also tested for conformance to IEC 60601-1-6:2010, IEC 60601-1-11:2015, IEC 60601-2-83:2019 including gap analysis demonstrating conformance to IEC 60601-2-57:2011.

Software Verification and Validation Testing Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The minor (A) level of concern was determined because malfunction of, or a latent design flaw in the software could not lead to a patient injury

8. USABILITY TESTING:

The sponsor conducted a Usability/Label Comprehension study to acquire data in order to evaluate and measure labeling comprehension, device usability, self-selection component, and training effectiveness by "intended users" of the Elipsa device.
The results of this testing on the final version of the labeling and instruction plan showed that the instructions were effective and intended users were able to understand the labeling and apply this information to device use for the primary operating functions of the device.

9. Conclusions

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 as safe, as effective, and performs as well as the referenced predicate devices.