March 12, 2024

Emoled, Srl
% Robert Swain
Principal Consultant
RESound Clinical Consulting LLC
19 Chipping Norton Lane
Bedford, New Hampshire 03110

Re: K240132
Trade/Device Name: EmoLED (v. 2-USA)
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: GEX
Dated: January 17, 2024
Received: January 17, 2024

Dear Robert Swain:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2024.03.12 09:56:46 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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)*
K240132

Device Name
EmoLED (v. 2-USA)

Indications for Use *(Describe)*
The EmoLED device is intended to provide photo therapeutic light to the body. The EmoLED device is generally indicated to treat dermatological conditions. The EmoLED device is specifically indicated to emit visible blue/violet light to treat moderate inflammatory acne vulgaris.

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

Prepared on: 2024-03-07

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EmoLED (v. 2-USA)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200659	Dermalux Tri-Wave MD	GEX
K232656	BLU TOTALE	OLP

Device Description Summary

21 CFR 807.92(a)(4)

EmoLED is a portable, reusable medical device powered by rechargeable lithium-ion batteries that illuminate six (6) LED light sources which emit non-coherent blue light between 415 ± 5 nanometers (nm). The EmoLED device emits a uniform and constant optical power intensity of 120 mW/cm2 over an area of approx. 50.3 cm2 (a circle of 8 cm in diameter) at a distance of 4 +/- 1 cm. The EmoLED device consists of:

- a polycarbonate body containing a software-controlled processor that controls the emission of light;
- a touch screen (display), placed in the front part of the body of the device that allows the operator to control the device;
- a multi-function (on/off) button, placed in the posterior part of the body of the device;

- a power jack and a micro-USB plug, placed on the left side of the body of the device;
- an optic part containing the LED light source, the LED's control board, an optical lens (optic head) and a distance sensor connected to the body which can be rotated by the operator up to 180° to project the light beam on the desired skin surface;
- accessories, which include a visual comfort screen and 24V power supply (with an integrated connection cable).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The EmoLED device is intended to provide photo therapeutic light to the body. The EmoLED device is generally indicated to treat dermatological conditions. The EmoLED device is specifically indicated to emit visible blue/violet light to treat moderate inflammatory acne vulgaris.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device is substantially equivalent to the primary predicate device. The subject device and primary predicate device have similar indications for use and intended use, intended users, and use environments, with minor differences that do not introduce new questions for safety and effectiveness.

The Dermalux Tri-Wave MD (the primary predicate device) provides phototherapeutic light energy from three distinct spectra; red light, blue light, and near infrared. The primary predicate device's indications for use states that each individual spectra is intended to treat specific dermatological conditions:

• The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris;

• The red light (633nm wavelength) is generally indicated for treatment of superficial, benign, vascular and pigmented lesions;

• The near-infrared light (830nm wavelength) is generally indicated for the temporary relieve of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

The indications for use for the EmoLED (the subject device) is limited to the blue light region of the visible light spectrum (415nm wavelength), and has the identical indications for use as the primary predicate device's blue light indication:

• The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The primary predicate and subject device have the same indications for use limited to the blue light region and the intended use to generally treat dermatological conditions and specifically treat moderate inflammatory acne vulgaris. The primary predicate device has additional indications for use involving red light (633nm wavelength) and near infrared light (830nm wavelength) for the treatment of conditions other than those identified for the blue light (415nm wavelength) indication, and which are independent of the indications for use involving the 415nm wavelength light. The use of the EmoLED device at 415nm wavelength for the same indications as the primary predicate device at the same wavelength does not raise new questions on safety and effectiveness, as the devices have substantially equivalent indications. This rationale should meet the requirements of 21 CFR 807.92(a)(5).

Technological Comparison

21 CFR 807.92(a)(6)

The Dermalux Tri-Wave MD primary predicate device (K200659) employs a total of 480 LEDs that emit blue light at a wavelength of 415 nm and produces a maximum power density of 40 mW/cm2. In K200659, the Dermalux Tri-Wave MD device was compared to the Phototherapy Systems device, cleared under K190938; the latter device has the same indications for use as the EmoLED and Dermalux Tri-Wave MD device (with relation to the use of blue light at 415nm wavelength). The Phototherapy Systems device blue light LEDs produce a maximum power density of 120 mW/cm2. The EmoLED employs 6 blue light LEDs that produce a maximum power density of 120 mW/cm2, identical to the Phototherapy Systems device. This indicates that based on the identical indications for use and the differential in the maximum power density between the Dermalux Tri-Wave MD and its predicate, the Phototherapy Systems device, there are no new questions of safety and effectiveness raised by this difference in technological characteristic. It is therefore reasonable to conclude that the difference in maximum power density between the EmoLED and the Dermalux Tri-Wave MD raises no new questions of safety and effectiveness, since this same difference failed to raise these questions when the Dermalux Tri-Wave MD was compared to its predicate (Phototherapy Systems).

The effective treatment area of the Dermalux Tri-Wave MD is 792 cm2, where the effective treatment area of the EmoLED device is approximately 50.3cm2, which represents the area of an 8 cm diameter circle. Given the intended use of treating dermatological conditions in general and moderate acne vulgaris specifically, focusing light energy within an 8 cm diameter circle on the face and/or

back/shoulders is appropriate since illuminating blue light on healthy skin provides no therapeutic benefit, and the purpose of the subject device is to treat the affected area. In the case of acne vulgaris, which most frequently affects the face and back/shoulders, a treatment area of 50.3 cm2 is appropriate with the intended use even if multiple, overlapping treatments are required on the back/ shoulders. The difference in effective treatment area between the subject and primary predicate device does not raise any new questions of safety and effectiveness as the products both achieve therapeutic benefit regardless of the size of the exposure area.

The standard dose of the subject device is 36.0 J/cm2. This is calculated by multiplying the output power (120 mW/cm2) by 300 seconds (5 minutes) of treatment time. This is compared to the dose of the primary predicate, which is 48 J/cm2 and is calculated by multiplying its output power (40 mW/cm2) by 1200 seconds (20 minutes) of treatment time. For both devices, the dosage can be adjusted by increasing or decreasing the exposure time of the blue light. The difference in the standard dosage (36 J/cm2 for the subject device, 48 J/ cm2 for the primary predicate device) does not raise new questions of safety and effectiveness.

The recommended treatment time for the EmoLED device is 5 minutes, compared to 20 minutes for the primary predicate device. A secondary predicate, the BLU TOTALE (K232656), is a hand-held OTC blue-light phototherapy device indicated for use in dermatology for the treatment of mild to moderate acne. The recommended treatment time for the BLU TOTALE is 4 minutes per treated area. This treatment time is comparable to the 5-minute treatment time for the EmoLED device. The 1 minute difference between the recommended treatment times between the subject device and the BLUE TOTALE secondary predicate device fails to raise new questions of safety and effectiveness.

The subject device is designed to deliver uniform, constant light energy to the skin when the source is 4 ± 1 cm from the surface of the skin. The distance sensor integrated into the optical head helps the operator establish this optimal distance. If the optical head is placed too close (<3 cm) or too far (>5 cm) from the skin's surface, the light energy will be paused until the optimal distance is re-established. The primary predicate device's minimum distance that the LED light panel should be to the skin surface is 2.5 cm, with no "optimal" distance identified. The minimum distance for the subject device is 3 cm, where the primary predicate's suggested minimum distance is 2.5 cm, both of which are very similar, with the minimum difference raising no issues with safety and effectiveness of the subject device.

The subject device has a much smaller footprint than the primary predicate device with the subject device being a hand-held device whereas the predicate device is a console that is wheeled into and out of position. The design of the subject device allows the user to achieve the indications for use to treat dermatological conditions, in general, and acne vulgaris, specifically, just as the primary predicate device's design does. Therefore, the differences in the footprint of the devices does not raise any questions of safety and effectiveness.

The subject device is powered using rechargeable lithium-ion batteries; a 24V charger (with integrated cable) is provided. When fully charged the subject device can provide approximately 150 minutes of treatment. All relevant electromagnetic compatibility testing and electrical safety testing has been performed and passed. The primary predicate device is powered by mains power. As both devices use electrical energy to power the devices for their intended use and the safety of the subject device has been validated through the applicable testing, there are no new questions of safety and effectiveness introduced through the different types of electrical energy sources for the devices.

While the intended use of the subject and primary predicate device is identical (with respect to blue light), there are notable differences when comparing technological characteristics between the two (e.g., output power, treatment area, treatment time, footprint, etc.) None of the differences in technological characteristics highlighted, however, raise any new questions of safety and effectiveness, and the performance of the subject device, as verified and validated through testing in accordance with relevant standards, has been demonstrated to be substantially equivalent to the primary predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing of the EmoLED device (v. 2) was conducted to verify that the device met all design specifications. The test results demonstrate that the EmoLED device complies with the following testing standards:

IEC 62471 First Edition 2006-07 (FDA #12-249) Photobiological safety of lamps and lamp systems
IEC 60601-2-57 Edition 1.0 2011-01 (FDA #12-242) Medical electrical equipment -- Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 62366-1 Edition 1.1 2020-06 Consolidated Version (FDA #5-129) Medical devices -- Part 1: Application of usability engineering to medical devices
CEI EN 60601-1-6/A1:2016 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability
ISTA 3E 2017 (FDA #5-128) Similar Packaged-Products in Unitized Loads of Truckload Shipment

No clinical testing has been performed to support this submission.

The EmoLED device was subjected to an identical series of nonclinical tests as its primary predicate device and the test results demonstrated that the EmoLED device performed as safe and as effective as the legally marketed primary predicate device.