July 8, 2024

Yassen Wellness LLC
Elias Michael
Head of R&D
1881 Von Karman Ave
Suite 1170
Irvine, California 92612

Re: K241293
Trade/Device Name: LED Light Therapy Device, ELIXIR MD™
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: April 12, 2024
Received: May 8, 2024

Dear Elias Michael:

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,

Yan Fu -S Digitally signed by Yan Fu -S
Date: 2024.07.08 17:25:11 -04'00'

for

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241293

Device Name
LED Light Therapy Device Model: ELIXIR MDTM

Indications for Use *(Describe)*
ELIXIR MDTM use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.

The blue light (417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The Yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.

The infrared light (835±15nm wavelength) is generally use for the temporary relief 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.

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.

510k Summary (K241293)

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Device Name- LED Light Therapy Device

Model Name- ELIXIR MD™

1. **Submitter's Identifications**
   Submitter's Name: YASSEN WELLNESS LLC
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   Contact Person: Ewan Yassen
   Contact Title: CEO
   Contact E-mail Address: ewan@yassenwellness.com
   Telephone: +1 646-546-8766

2. **Correspondent's Identifications**
   Correspondent Name: YASSEN WELLNESS LLC
   Address: 1881 Von Karman Ave, Suite 1170 Irvine, CA 92612 USA
   Contact Person: Micheal Elias
   Contact Title: Head of R&D
   Contact E-mail Address: Michaelelias@yassenwellness.com
   Telephone: +1(949)695-7727

3. **Date Prepared**
   06 July 2024

4. **Name of the Device**

Device Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Trade Name: LED Light Therapy Device

Model: ELIXIR MD™

510(K) Number: K241293

Classification Panel: General & Plastic Surgery

Product Code: GEX

Device Classification: Class II

Regulation Number: 21 CFR878.4810

5. **The Predicate Device:**
   K222751 LED Light Therapy Device, KN-7000L
6. **Device Description**

The ELIXIR MD™ uses specific wavelengths of light, produced by LEDs (light emitting diodes), to manage aesthetic conditions.

The device produces light in the red-light region of the spectrum (633 ± 10m), in the blue light regions of the light spectrum (417 ± 10m), the yellow light area (590 ± 10nm) and the infrared light region of the light spectrum (835 ± 15m).

The ELIXIR MD™ is equipped with two irradiators. The RBY irradiator has five panels, each of which emits three different colors of light sources (red light, blue light, yellow light); The RBI irradiator has five panels. Each panel emits three different colors of light sources (red light, blue light, infrared light).

7. Indications for Use

ELIXIR MD™ use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.

The blue light (417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The Yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.

The infrared light (835±15nm wavelength) is generally use for the temporary relief 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.

8. Summary of Substantial Equivalence

A comparison between the YASSEN LED Light Therapy Device ELIXIR MD™ and predicate devices have been compared with respect to indication use, technological characteristics, performance testing, and applicable standards. The subject does not raise any significant differences with the predicate device, which affects the safety and performance of the device.

Table 1: Comparison of characteristics

Item	Proposed Device	Predicate Device	Details of equivalence
Product Code	GEX	GEX	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Proprietary Name	LED Light Therapy Device	Photodynamic Therapy Device	-
Model	ELIXIR MD™	KN-7000L	-
Manufacturer	YASSEN WELLNESS, LLC.	Xuzhou Kernel Medical Equipment Co., Ltd.	-
Indications of use	LED Light Therapy Device, ELIXIR MD™ use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.	LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.	Same

Item	Proposed Device	Predicate Device	Details of equivalence
	The Yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (835±15nm wavelength) is generally use for the temporary relief 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 Yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (835±15nm wavelength) is generally use for the temporary relief 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	
Wavelength(s) (nm)	RBY irradiator: (Red light 633 ± 10nm, blue light 417 ± 10nm, yellow light 590 ±10nm). RBI irradiator: (Red 633 ± 10nm, blue 417 ± 10nm, infrared 835 ± 15nm)	RBY irradiator : (Red light 633 ± 10nm, blue light 417 ± 10nm, yellow light 590 ±10nm). RBI irradiator: (Red 633 ± 10nm, blue 417 ± 10nm, infrared 835 ± 15nm)	Same
Panel Type	RBY Irradiator has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; yellow light: 465EA LEDs;	RBY Irradiator has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; yellow light: 465EA LEDs;	Same

Item	Proposed Device	Predicate Device	Details of equivalence
	RBI irradiator: has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; infrared: 465EA LEDs; The panels may emit the three light (red, blue infrared) individual or in combination	RBI irradiator: has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; infrared: 465EA LEDs; The panels may emit the three light (red, blue infrared) individual or in combination	
Output Power	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is 0.5W	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is 0.5W	Same
Maximum power density in Mw (mW/CM^2)	Red light: 20～96 mw/cm² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm²	Red light: 20～96 mw/cm ² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm²	Same
Standard dose in Joules	Red light: 20～96 mw/cm² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ²	Red light: 20～96 mw/cm ² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ²	Same

Item	Proposed Device	Predicate Device	Details of equivalence
	Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm² Red/IR: 199J/cm2 Blue/IR: 228J/cm2	Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm² Red/IR: 199J/cm2 Blue/IR: 228J/cm2	
Adjustable dose range	Red light: 20～96 mw/cm² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 20～166mW/cm² , Blue/IR: 10～190mW/cm²	Red light: 20～96 mw/cm ² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 20～ 166mW/cm², Blue/IR: 10～ 190mW/cm²	Same
Number of LEDs	Red light:465EA LEDs; Blue light: 470EA LEDs; Yellow light: 465EA LEDs; Infrared: 465EA LEDs;	Red light:465EA LEDs; Blue light: 470EA LEDs; Yellow light: 465EA LEDs; Infrared: 465EA LEDs;	Same
Effective irradiation area: (CM^2)	900 cm²±10%	900 cm²±10%	Same
Pulse mode parameter	Turn “ON” and “OFF” at a fixed rate	Turn “ON” and “OFF” at a fixed rate	Same
Pulse mode duration	For 2Hz flashing interval time is 0.5s	For 2Hz flashing interval time is 0.5s	Same

Item	Proposed Device	Predicate Device	Details of equivalence
	For 5Hz flashing interval time is 0.2s For 10Hz flashing interval time is 0.1s	For 5Hz flashing interval time is 0.2s For 10Hz flashing interval time is 0.1s	
Structural style	Wheeled	Wheeled	Same
Structure composition	Main frame, irradiator, lifting frame	Main frame, irradiator, lifting frame	Same
Power supply	AC 100-240 50/60Hz	AC 100-240 50/60Hz	Same
Treatment time	20min (Recommended treatment time)	20min (Recommended treatment time)	Same
Operation interface	Display screen	Display screen	Same
Software	Yes	Yes	Same
Safety classification	Class I	Class I	Same
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	Same

9. Substantial Equivalence discussion

There are no differences between the subject device and the predicate device. The subject and predicate devices are similar in indicated use, and technical specifications. The subjective device meets the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57, and IEC 62471 standards because of the same design as the predicate device. There are no technological differences that raise new or different questions of safety or effectiveness.

10. Non-Clinical Tests Performed

Electrical Safety and Electromagnetic Compatibility Testing – The device has been tested and meets the following standard requirements of medical equipment:

● IEC60601-1: 2005+2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

● IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

● IEC 60601-2-57:2011 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

Photobiological Safety Testing – The device has been tested and comply with IEC 62471:2006, Photobiological safety of lamps and lamp systems, 1st edition.

This IEC standard incorporates the principles of the following ANSI IESNA recommended practices:

● RP 27.1:2005 Recommended practice for photobiological safety for lamps and lamp systems -General requirements.

● RP 27.2:2000 Recommended practice for photobiological safety for lamps and lamp systems -Measurement techniques.

● RP-27.3:2007 Recommended practice for photobiological safety for lamps and lamp systems –Risk group classification and labeling.

Software Verification and Validation – Software documentation consistent with moderate level of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Bench Test Summary:

Performance Test (Appearance; Spectral peak wavelength; Effective irradiance; Timing and functions; Effective radiation area; Stand adjustment; Changeable treatment head; Uniformity of effective red light irradiance; Working noise; Protective grounding impedance; Continuous leakage current at normal operating temperature; Dielectric strength at normal operating temperature; Packing inspection).

The device passed all the tests mentioned above.

11. Conclusion

Based on comparing to predicate device, the proposed device of LED Light Therapy Device, Elixir MD™ are determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness