April 10, 2024

Shenzhen Kaiyan Medical Equipment Co., Ltd
Alain Dijkstra
Official Correspondent
Building#3 and Building#5, 40th of Fuxin Street, Huaide
Community Fuyong Town, Baoan District
Shenzhen, Guangdong 518103
China

Re: K240089
Trade/Device Name: Face Patches (MT-12MA, MT-12MC)
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: OHS, OLP, GEX
Dated: January 9, 2024
Received: January 12, 2024

Dear Alain Dijkstra:

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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.04.10 14:46:04 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K240089

Device Name
Face Patches (MT-12MA, MT-12MC)

Indications for Use *(Describe)*
Face Patches (Model: MT-12MA) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.
Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles).

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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K240089

510(k) Summary of K240089

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
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Application Correspondent:
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2. Subject Device Information:

Trade Name: Face Patches, model: MT-12MA, MT-12MC
Classification Name: Over-The-Counter Powered Light Based Laser For Acne. Light based over the counter wrinkle reduction, Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP, GEX
Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K230720)
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LUSTRE 3XPRESS Light Beauty Therapy patches, model: PR6001, PR5001
Classification Name: Over-The-Counter Powered Light Based Laser For Acne. Light based over the counter wrinkle reduction, Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K221946)
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED LIGHT THERAPY MASK, model: MK66R-B
Classification Name: Light based over the counter wrinkle reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 3 (K200104)
Sponsor: RAJA Trading Company, Inc.
Trade Name: OxyLight
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: GEX, GFE
Regulation Number: 21 CFR 878.4810, 21 CFR 878.4820
Regulation Class: II

4. Device Description

The Face Patches, Model: MT-12MA and MT-12MC is an over-the-counter light emitting diode (LED) device.
Model: MT-12MA can emits 415nm and 630nm energy to treat mild to moderate acne. There is a total of 6 LEDs, providing a power intensity of approximately 30 mW/cm^2.
Model: MT-12MC has 3 modes (mode 1: 630+415nm, mode 2: 630+830nm, mode 3: 590nm), it can emit 630nm and 415 nm energy to treat mild to moderate acne and provide approximately 30 mW/cm^2; 630nm and 830nm energy to treat full-face wrinkles and provide approximately 35 mW/cm^2; and 590nm energy to treat wrinkles and provide approximately 35 mW/cm^2. There is a total of 18 LEDs.
The device components include the device containing two face patches, a controller, a charging cable, 120 Mini Dots, goggles and user manual. The user pastes the device on the treatment area, and the device will shut down automatically after a 3-minute after finishing treatment. Users should adjust the treatment time based on different modes and actual treatment situations. The device has one button, and delivery of therapy requires the operator to depress a physical switch on the device.

5. Intended Use / Indications for Use

Face Patches (Model: MT-12MA) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.
Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles).

6. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device	Predicate device (K230720)	Predicate device (K221946)	Predicate device (K200104)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	Light Tree Ventures Europe B.V.	RAJA Trading Company, Inc.	--
Trade Name	Face Patches	LUSTRE 3XPRESS Light Beauty Therapy patches	LED LIGHT THERAPY MASK	OxyLight	--
Model	MT-12MA, MT-12MC	PR6001, PR5001	MK66R-B	--	--
510 (K) Number	K240089	K230720	K221946	K200104	--
Regulation Class	Class II	Class II	Class II	Class II	Same
Indications for Use / Intended	Face Patches (Model: MT-12MA)	The LUSTRE 3XPRESS Light	The LED LIGHT THERAPY	The Oxylight is intended for	Different, note 1

Elements of Comparison	Subject device	Predicate device (K230720)	Predicate device (K221946)	Predicate device (K200104)	Remark
use	is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne. Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles).	Beauty Therapy patches (Model: PR6001, PR5001) is an Over-the-Counter (OTC) device intended for the treatment of mild to moderate acne.	MASK (MK66R-B) is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	dermatological use by physicians and healthcare professionals for the following: LED Technology is intended for: -Blue LED – 465nm – to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. -Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions. -Yellow LED 590nm - treatment of periorbital wrinkles and rhytides. Microdermabrasion is intended for exfoliation of the skin. Oxygen spray is intended to refresh the skin.	
Power Source	Controller: 3.6V, 65mAh lithium battery, 0.234Wh	Input: 100-240Va.c., 50Hz/60Hz; output: 5Vd.c., 2A	Input: 100-240Va.c., 50Hz/60Hz, Output: 5Vd.c., 2A.	not available	Different, note 2
Wavelengths	MT-12MA: 630 ± 10nm 415 ± 10nm MT-12MC: 415nm ± 10nm, 630nm ± 10nm, 830nm ± 10nm, 590nm ± 10nm	630 ± 10nm 415 ± 10nm	Red: 630±5nm NIR: 830nm	590 nm +/- 5nm	Similar, note 3
Irradiance source	LED	LED	LED	LED	Same
LED number	For MT-12MA: 415nm: 6 630nm: 6	Blue: 12 Red: 12 Total 24	630+/-5nm: 66 830nm: 66	not available	Different note 4

Elements of Comparison	Subject device	Predicate device (K230720)	Predicate device (K221946)	Predicate device (K200104)	Remark
	For MT-12MC: 415nm: 6 630nm: 12 (two type) 830nm: 6 590nm: 6 Total 18 LEDs				
Intended location Use	Face	Face	Face	Face	Same
Irradiance (mW/cm^2)	For MT-12MA: 630nm: 5 415nm: 25 630+415nm: 30 For MT-12MC: 630nm (type 1): 5 415nm: 25 Mode 1 - total: 30 830nm: 15 630nm (type 2): 20 Mode 2 - total: 35 Mode 3 - 590nm: 35	Red: 5 Blue: 25 630+415nm: 30	630+/-5: 15-20 830nm: 10-15 630+830nm: 30	Yellow (590nm): 35	Similar, note 5
Dose / per time(J/cm^2)	For MT-12MA: 630+415nm: 5.4 For MT-12MC: 630+415nm: 5.4 630+830nm: 18.9 590nm: 44.1	630+415nm: 5.4	630+830nm: 18	590nm: 42	Similar, note 5
LED distribution	Uniform distribution	Uniform distribution	Uniform distribution	Uniform distribution	Same
Treatment Time	For MT-12MA (630+415nm): 3 minutes per treatment For MT-12MC (mode 1 - 630+415nm): 3 minutes per treatment For MT-12MC (mode 2 - 630+830nm): 9 minutes per	3 minutes per treatment	10 minutes per treatment	20 minutes	Similar, note 5

Elements of Comparison	Subject device	Predicate device (K230720)	Predicate device (K221946)	Predicate device (K200104)	Remark
	treatment For MT-12MC (mode 3 - 590nm): 21 minutes per treatment				
EMC	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	IEC 60601-1-2	Same
Safety	IEC60601-1 IEC60601-2-57 IEC60601-1-11 IEC62471 IEC 60601-1-6	IEC 60601-1 IEC 60601-2-57 IEC 60601-1-11 IEC 62471	IEC 60601-1 IEC 60601-2-57 IEC 60601-1-11 IEC 62471 IEC 62366-1 & IEC 60601- 1-6	IEC 60601-1, EN 60601-1-2	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23 ISO 10993-11	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 ISO 10993-11	ISO 10993-1, ISO 10993-5, ISO 10993-10	not available	Same

Comparison in Detail(s):

Note 1: Although the “Indications for Use / Intended use” is a little different from the predicate devices, the acne removal function of the model MT-12MA and MT-12MC (mode1) of subject device is consistent with predicate device (K230720), the wrinkle removal function of the model MT-12MC (mode 2) of subject device is consistent with predicate device (K221946), the wrinkle removal function of the model MT-12MC (mode 3) of subject device is consistent with predicate device (K200104). So, this difference will not affect the safety and effectiveness of the subject device.

Note 2: Although the “Power Supply” is a little different from the predicate devices, they all complied with the IEC 60601-1, IEC 62133-2, and IEC 60601-1-2 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

Note 3: The wavelengths of the subject device can be covered by the predicate device. The wavelength of MT-12MA and MT-12MC Mode 1 is 630nm and 415nm, which is consistent with the predicate device 1 (K230720); The wavelength of MT-12MC Mode 2 is 830nm and 630nm which is consistent with the predicate device 2 (K221946); The wavelength of MT-12MC Mode 3 is 590nm which is consistent with the predicate device 3 (K200104).
So, the treatment wavelength of the subject device is acceptable.

Note 4: Although the “Number of LEDs” is different from the predicate devices, it will not change the irradiance which is similar. So, these differences will not raise any safety or effectiveness issues.

Note 5: Although the “Irradiance”, “Dose / per time” and “Treatment Time” are a little different from the predicate devices, the values of each treatment for these parameters are very close. Dose is equal to Irradiance (W/cm^2) * Time (s). Through calculation, it can be concluded that the dose of the subject device at 630+415nm is 0.03 * 3 * 60=5.4J/cm^2, which is consistent with the dose of the predicate device (K230720) at 0.03 * 3 * 60=5.4J/cm^2; The dose of subject device 830+630nm is 0.035 * 9 * 60=18.9J/cm^2, which is similar to the dose of predicate device (K221946) of 0.03 * 10 * 60=18J/cm^2, and the dose of

590nm is 0.035 * 21 * 60=44.1J/cm^2, which is similar to the dose of predicate device (K200104) of 0.035 * 20 * 60=42J/cm^2. So, these differences will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment - Part 1: 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.
- IEC 60601-2-57 Edition 1.0 2011-01 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

2) Biocompatibility Test

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), ISO 10993-23 (Skin Irritation) and ISO 10993-11 (Acute Systemic Toxicity and Material-mediated Pyrogens) and USP 151.

3) Software verification and validation

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 software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

Usability testing was conducted on the Face Patches (Models: MT-12MA, MT-12MC), which complies with IEC 62366-1 and IEC 60601-1-6.

5) Light output

The Light output test validated that the output of light from the devices are the same as stated in the specifications.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: April 9, 2024

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K230720, K221946 and K200104.