April 22, 2026

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% Anna He
Regulations Manager
Shenzhen Kaiyan Medical Equipment Co., Ltd.
Bldg.#3 And Bldg.#5, 40th Of Fuxin St.
Huaide Community, Fuyong Town, Baoan District, Shenzhen
Shenzhen,
China

Re: K260150
Trade/Device Name: LED Facial Mask (MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C)
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
Dated: December 3, 2025
Received: January 20, 2026

Dear Anna He:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.04.22 21:51:07 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260150

Device Name
LED FACIAL MASK (MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C)

Indications for Use *(Describe)*
LED Facial Mask (Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C), is intended to emit energy in the red and near-infrared spectrum for treatment of full-face 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K260150

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: NOOĀNCE
Establishment Registration Number: 3036498001
Address: 22 rue Beaujon 75008 Paris France
Contact Person (including title): Joyce Herail (Deputy CEO)
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E-mail: quality@nooance.com

Application Correspondent:

Contact Person: Océane Phan-Tan-Luu
Company: NOOĀNCE
Address: 22 rue Beaujon 75008 Paris France
Tel: +33 06 61 38 08 73
Fax: N/A
Email:quality@nooance.com

2. Subject Device Information:

Trade Name: LED FACIAL MASK (Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C)
Classification Name: Light Based Over The Counter Wrinkle Reduction (OHS)
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K201107)
Sponsor: GTG Wellness Co., Ltd.
Trade Name: OPERA LEBODY (Model: OLG-200, OLZ-200)
Classification Name: Light Based Over the Counter Wrinkle Reduction (OHS);
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K241933)
Sponsor: HigherDOSE LLC
Trade Name: HIGHERDOSE Red and Infrared Light Mask (MK-66L)
Classification Name: Light Based Over the Counter Wrinkle Reduction (OHS)
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

LED FACIAL MASK (Model: Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C) is a home-use led phototherapy device. The LED FACIAL MASK is an over-the-counter (OTC) device that can be sold directly to the public.

For MJ-66DB
The LED FACIAL MASK (Model: MJ-66DB) is an at-home wearable LED phototherapy Face Mask with two proven wavelengths of light 633nm (Red Light) and 830nm (near Infra-Red Light). Both of these lights are known to treat wrinkles. The LED FACIAL MASK is a silicone mask that contains light-emitting diodes (LEDs) with pulses at 22kHz.

For MK-99 and MK-99A
The LED FACIAL MASK (Model: MK-99 and MK-99A) is an at-home wearable LED phototherapy Face Mask with two proven wavelengths of light 633nm (Red Light, ±2nm) and 830nm (near Infra-Red Light, ±2nm). Both of these lights are known to treat winkles. The LED FACIAL MASK is a flexible silicone mask that contains light-emitting diodes (LEDs) and controller with pulses at 2kHz.

For MK-99M and MJ-66C
The LED FACIAL MASK (Model: MK-99M and MJ-66C) is an at-home wearable LED phototherapy Face Mask with two proven wavelengths of light 633nm (Red Light, ±2nm) and 830nm (near Infra-Red Light, ±2nm). Both of these lights are known to treat wrinkles. The LED FACIAL MASK is a silicone mask that contains light-emitting diodes (LEDs) and controller with pulses at 22kHz.

5. Intended Use / Indications for Use

LED Facial Mask (Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C), is intended to emit energy in the red and near-infrared spectrum for treatment of full-face 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 K260150	Predicate device K201107	Predicate device K241933	Remark
Manufacturer	NOOĀNCE	GTG Wellness Co., Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	--
510 (K) Number	Pending	K201107	K241933	--
Device Name	LED FACIAL MASK (Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C)	OPERA LEBODY (Model: OLG-200, OLZ-200)	HigherDose Light Face Mask (MK66-L)	--

Elements of Comparison	Subject device K260150	Predicate device K201107	Predicate device K241933	Remark
OTC/Rx	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Same
Product Code	OHS	OHS	OHS	Same
Anatomical Sites	Face	Full Face	Face	Same
Environment of Use	Home	Home	Home	Similar
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use / Intended use	LED Facial Mask (Model: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C), is intended to emit energy in the red and near-infrared spectrum for treatment full -face wrinkles.	OPERA LEBODY is an over the counter device that is intended for the use in the treatment of full face wrinkles.	The HIGHERDOSE Red And Infrared Light Mask (Model: MK-66L) is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	Same
Housing Materials of main unit	MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C: Silicone Controller: PC+ABS	Silicone, ABS plastics	Silicone	Different, note1
Power Source	MJ-66DB: Lithium-ion, Battery: 3.7V, 1200mAh MK-99: Lithium-ion, Battery: 3.7V, 3600mAh MK-99A: Lithium-ion, Battery: 3.7V, 3700mAh MK-99M: Lithium-Ionen, Battery: 3.7V, 5200mAh MJ-66C: Lithium-ion, Battery: 3.7V, 5200mAh	not mentioned	Lithium battery	Different, note 2

Elements of Comparison	Subject device K260150	Predicate device K201107	Predicate device K241933	Remark
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Same
Type of Energy	LED	LED	LED	Same
Treatment time	10 minutes per time, 50 minutes per week	10 minutes daily, 3 days per week for 8 weeks.	10 minutes, 3-5 times per week	Same
Software/ Firmware /Microprocessor Control?	Yes	Yes	Yes	Same
LED wavelength	Red: 633nm(±2nm) NIR: 830nm(±2nm)	Red: 630nm IR: 830nm	Red: 630±10nm NIR: 830nm±10nm	Same
Irradiance	MJ-66DB: Red light: 30mW/cm^2 (±10%) NIR: 15mW/cm^2 (±10%) MK-99: Red light: 15mW/cm^2 (±10%) NIR: 15mW/cm^2(±10%) MK-99A: Red light:35mW/cm^2 (±10%) NIR:15mW/cm^2(±10%) MK-99M: Red light:35mW/cm^2 (±10%) NIR:15mW/cm^2(±10%) MJ-66C Red light:35mW/cm^2 (±10%) NIR: 15mW/cm^2 (±10%)	Total (Red+NIR): 50mW/cm^2	Red: 20mW/cm^2 NIR: 30mW/cm^2	Different, note 3
Visible light LEDs	Yes	Yes	Yes	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC60601-1-2	Same
Safety	Compliant with IEC 60601-1, IEC 60601-1-11, IEC 62471, IEC 60601-2-57	Compliant with IEC 60601-1:2005, IEC 60601-1-2 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC 62471, IEC 0601-2-57	Same

Note 1: Although the housing materials of main unit is different from the predicate devices, it complies with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-23 (Irritation). So, the difference will not raise any safety or effectiveness issue.

Note 2: Power source specifications are similar to the predicate devices. The subject device is in compliance with IEC 60601-1, IEC 60601-1-11, IEC 62133-2 and IEC 60601-1-2 requirement for the product.

Note 3: Although the irradiance is a little different from the predicate devices, they are within the range of previous cleared devices, so the differences will not raise any safety or effectiveness issue. The irradiance of the red light is in between the irradiance of K201107 and the irradiance of K241933.

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 for 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
- 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 component materials of the subject device are identical to the corresponding component materials of the previously cleared devices (K241933) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

There is no change in biocompatibility since the previously cleared devices. Therefore, based on this information, the subject device can comply with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-23 (Irritation).

3) Software verification and validation

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff”. The

software for this device was considered as a Basic Documentation Level, 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 LED FACIAL MASK (Models: MJ-66DB, MK-99, MK-99A, MK-99M, MJ-66C).

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: March 27, 2026

9. Final Conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K201107 and K241933.