August 7, 2025

Shenzhen Liyoutong Technology Co., Ltd.
℅ Riley Chen
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K251667
Trade/Device Name: LED Light Therapy Mask (M01, M02, M06, M07, M08, M09)
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
Dated: May 26, 2025
Received: May 30, 2025

Dear Riley Chen:

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.

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.08.07 12:39:37 -04'00'

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251667 |

Please provide the device trade name(s).

LED Light Therapy Mask (M01, M02, M06, M07, M08, M09)

Please provide your Indications for Use below.

☐M01, M02, M06, M07, M08:
Red light: Treatment of full-face wrinkles.
☐Red+Infrared Light: Treatment of full-face wrinkles.
☐Amber light: Treatment of full-face wrinkles.
☐Blue light: Treatment of mild to moderate inflammatory acne.

M09:
☐Red+Infrared Light: Treatment of full-face wrinkles.
☐Amber light: Treatment of full-face wrinkles.
Mixed light: Treatment of mild to moderate inflammatory acne.

Please select the types of uses (select one or both, as applicable).

☐ Prescription Use (Part 21 CFR 801 Subpart D)
☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251667

# 510(k) Summary

Prepared on: 2025-05-30

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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| Correspondent Contact Telephone | +86 13660660449 |
| Correspondent Contact | Ms. Riley Chen |
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | LED Light Therapy Mask (M01, M02, M06, M07, M08, M09) |
| Common Name | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Classification Name | Light Based Over The Counter Wrinkle Reduction |
| Regulation Number | 878.4810 |
| Product Code(s) | OHS, OLP |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K241857 | LED Light Therapy Device | OHS,OLP, ILY |
| K192295 | LED THERAPY DEVICE | OHS,OLP |
| K223544 | LED light therapy mask | OHS,OLP, ILY |

## Device Description Summary

21 CFR 807.92(a)(4)

LED Light Therapy Mask is a home use wearable LED phototherapy device which can help reduce facial wrinkles and mild to moderate inflammatory acne. LED Light Therapy Mask is consisting of main unit (mask), controller, Type-C charging cable and so on. There are 4

kinds of light, including Red light (wavelength 630nm), Blue light (wavelength 415nm), Amber light (wavelength 605nm), Infrared light (wavelength 850nm).
The M01, M02, M06, M07, M08 output 4 kinds of treatment modes: red+infrared, red, amber, blue. The M09 outputs 3 kinds of treatment modes: red+infrared, amber, blue+red+infrared.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

M01, M02, M06, M07, M08:
Red light: Treatment of full-face wrinkles.
Red+Infrared Light: Treatment of full-face wrinkles.
Amber light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.

M09:
Red+Infrared Light: Treatment of full-face wrinkles.
Amber light: Treatment of full-face wrinkles.
Mixed light: Treatment of mild to moderate inflammatory acne.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device is comparable to the indications for use of the predicate devices.

## Technological Comparison

21 CFR 807.92(a)(6)

The technical characteristics of LED Light Therapy Mask (Models: M01, M02, M06, M07, M08, M09)
are substantially equivalent to the predicate device in the following aspects:
1. the indications for use of LED Light Therapy Mask are within the range of the predicate and reference devices.
2. similar power supply: the product uses lithium batteries, which were tested according to FDA guidance documents and the requirements of IEC 62133-2, the tests are all passed.
3. same wavelength: the LED Light Therapy Mask has the same wavelengths (red: 630nm, amber: 605nm, blue: 415nm, infrared: 850nm) as K241857 and K192295, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so it will not raise any safety or effectiveness issue.
4. similar irradiance: though the irradiance of subject device is a little different from the predicate device and reference devices, the irradiance of subject device is within the range of the minimum and maximum value of the predicate device and reference devices, and the subject device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue. The evaluation process is as follows:
a. The Red+IR, Red, Amber irradiance of subject device is similar to the predicate device (K241857)
b. The mixed light irradiance of subject device is the same as reference device 2 (K223544)
c. The blue light irradiance of subject device is within the range of the predicate device (K241857) and reference device 1 (K192295)
5. the same safety features: Type BF applied part.
6. dimension and weight: though the dimension and weight are a little different from the predicate device and reference devices, this difference is insignificant and do not raise any safety or effectiveness problems.

Therefore,the LED Light Therapy Mask is substantially equivalent to its predicate device and reference predicate devices.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination.
ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 60601-1:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
IEC 60601-1-11:2020, 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 60601-2-83: 2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
IEC 62471: 2006, Photobiological safety of lamps and lamp systems

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.