



January 28, 2025

Shenzhen Rainbow Technology Co., Ltd.
% Jilan Luo
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: K243423

Trade/Device Name: LED Light Therapy Mask (Model(s): RB-008, RB-030, RB-081, RB-008G, RB-008GB, RB-008J, RB-008JB)

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, IL Y

Dated: October 31, 2024

Received: November 4, 2024

Dear Jilan Luo:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.01.28 16:52:13
-05'00'

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

Indications for Use

510(k) Number (if known)

K243423

Device Name

LED Light Therapy Mask (Model(s): RB-008, RB-030, RB-081, RB-008G, RB-008GB, RB-008J, RB-008JB)

Indications for Use (Describe)

- Red+Infrared light: Treatment of full-face wrinkles.
- Red light: Treatment of full-face wrinkles.
- Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Red+Blue light: Treatment of mild to moderate inflammatory acne.

The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

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) #: K243423

510(k) Summary

Prepared on: 2025-01-27

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Shenzhen Rainbow Technology Co.,Ltd.
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Correspondent Contact Telephone	+86 13535208704
Correspondent Contact	Ms. Jilan Luo
Correspondent Contact Email	jilan.luo@qq.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	LED Light Therapy Mask (Model(s): RB-008, RB-030, RB-081, RB-008G, RB-008GB, RB-008J, RB-008JB)
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	21 CFR 878.4810, 21 CFR 890.5500
Product Code(s)	OHS, OLP, ILY

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, IL'
K230351	LED Facial Mask	OHS, OLP
K241102	Luna 4 Plus	OHS, NFO
K160691	Acne Light Therapy Wand	OLP
K223544	LED Light Therapy Mask	OHS, OLP, IL'

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The LED Light Therapy Mask adopts light emitting diodes (LED) in the infrared, red and blue spectrum to irradiate on the skin. The face will absorb the light energy to achieve the therapeutic effects. The LED Light Therapy Mask is applied directly to the skin to ensure consistent administration of light during each treatment. LED Light Therapy Mask is a home use wearable LED phototherapy device which can help reduce wrinkles and acne and provide topical heating. It is consisting of main unit(mask), controller, Type-C charging cable and so on.

The RB-081 outputs 5 kinds of treatment modes: red+infrared, red, infrared, blue, red+blue light. The RB-030 outputs 4 kinds of treatment modes: red+infrared, red, infrared, blue light. The RB-008 outputs 3 kinds of treatment modes: red+infrared, red, blue light. The RB-008G/RB-008GB/RB-008J/RB-008JB output 4 kinds of treatment modes: red+infrared, red, blue, red+blue light.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

☑Red+Infrared light: Treatment of full-face wrinkles.

☑Red light: Treatment of full-face wrinkles.

☑Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

☑Blue light: Treatment of mild to moderate inflammatory acne.

☑Red+Blue light: Treatment of mild to moderate inflammatory acne.

The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The LED Light Therapy Mask have the same indications for use as the predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technical characteristics of LED Light Therapy Mask (Models:RB-008, RB-030, RB-081, RB-008G, RB-00008GB, RB-008J, RB-008JB) are substantially equivalent to the predicate devices in the following aspects:

1.the indications for use of LED Light Therapy Mask are within the range of all predicate 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: 620nm, blue: 460nm, infrared: 850nm) as K223544 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 predicate 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. Red+IR light: the irradiance of subject device (45.5mW/cm²) is between the range of K241857 (30mW/cm²) and K241102 (63mW/cm²).

b. Red light: the irradiance of subject device (53.2mW/cm²) is within the range of the red light irradiance (31~75mW/cm²) of K230351.

c. Infrared light: the irradiance of subject device (4mW/cm²) is the same as the K223544.

d. Blue light: the irradiance of subject device (58.7mW/cm²) is within the range of the blue light irradiance (15~63mW/cm²) of K230351.

e. Red and blue light: the irradiance of subject device (33.6mW/cm²) is similar with the K160691(34mW/cm²).

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\(b\)](#)

Non-clinical tests have been conducted to verify that the LED Light Therapy Mask meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device complies with the following standards:

1. IEC 60601-1:2020, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

2. IEC 60601-1-2:2021, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

3. IEC 60601-1-11:2020, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance --