



December 8, 2025

Guangdong Ace-Tec Co., Ltd.
% Tracy Che
Registration Engineer
Feiyong Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center,
3101-90 Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K252994

Trade/Device Name: LED Therapy Mask (SR11CM, SR11CM1, SR11CM2, SR11CM3, SR11CM4,
SR11CM5, SR11CM6, SR11CM7, SR11CM8)

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: September 17, 2025

Received: September 18, 2025

Dear Tracy Che:

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: 2025.12.08

09:51:21 -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

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

K252994

?

Please provide the device trade name(s).

?

LED Therapy Mask (SR11CM, SR11CM1, SR11CM2, SR11CM3, SR11CM4, SR11CM5, SR11CM6, SR11CM7, SR11CM8)

Please provide your Indications for Use below.

?

ACNE mode (red light + blue light): Treatment of mild to moderate inflammatory acne.

FIRM mode (yellow light): Treatment of full-face wrinkles.

WRINKLE mode (red light + IR light): Treatment of full-face wrinkles.

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) #: **K252994**

510(k) Summary

Prepared on: 2025-12-08

Contact Details

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

Applicant Name	GUANGDONG ACE-TEC CO., LTD
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Applicant Contact	Mr. Fate Chen
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Correspondent Name	FEIYING DRUG & MEDICAL CONSULTING TECHNICAL SERVICE GROUP
Correspondent Address	Rm 2401 Zhenye International Business Center, No. 3101-90, Qianhai Road Shenzhen Guangdong 518052 China
Correspondent Contact Telephone	+86 18027206248
Correspondent Contact	Ms. Tracy Che
Correspondent Contact Email	1273487536@qq.com

Device Name

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

Device Trade Name	LED Therapy Mask (SR11CM, SR11CM1, SR11CM2, SR11CM3, SR11CM4, SR11CM5, SR11CM6, SR11CM7, SR11CM8)
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
K242796	CryoGlow (FW3XXXX)	OHS, OLP
K231555	LUMA patches (Blemish & Revive)	OHS, OLP
K240089	Face Patches models MT-12MA, MT- 12MC	OHS, OLP
K242151	Radiant Renewal Skincare Wand Models: HD-44, HD-44A, HD-44B, HD-69, HD-69A	OHS, OLP

Device Description Summary

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

The LED Therapy Mask (Models: SR11CM, SR11CM1, SR11CM2, SR11CM3, SR11CM4, SR11CM5, SR11CM6, SR11CM7, SR11CM8) is an Over-the-Counter (OTC), home-use, wearable LED phototherapy device, and intended for the use of treating full-face wrinkles and mild to moderate acne. Light radiates from the inner surface of the device onto the face. This light is generated by LED with four different spectrum wavelengths: red (630nm), infrared (830nm), yellow (590nm) and blue (415nm). The LED Therapy Mask is consisting of main unit (mask, including eye shield), controller, USB charging cable and head strap.

The device is powered by rechargeable Li-battery and controlled by a controller that is connected to the main unit. The device's power-on/off, mode switch can be operated by the controller. The device will automatically shut down when the treatment time is over.

Intended Use/Indications for Use

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

ACNE mode (red light + blue light): Treatment of mild to moderate inflammatory acne.

FIRM mode (yellow light): Treatment of full-face wrinkles.

WRINKLE mode (red light + IR light): Treatment of full-face wrinkles.

Indications for Use Comparison

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

The subject device and predicate devices have the same indications for use, both are intended for wrinkle and mild-to-moderate acne reduction.

Technological Comparison

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

The subject device and predicate devices have similar technological characteristics:

- 1) They all use LEDs as the light source;
- 2) They all adopt the design of a mask which can cover the entire face;
- 3) They have the same wavelength, which are red (630nm), infrared (830nm), yellow (590nm) and blue (415nm).

The main differences between the subject device and predicate devices are:

- 1) Power supply: The subject device lithium battery has been tested as per IEC 62133-2, and the device has been assessed for electrical safety, so this difference does not raise any safety or effectiveness questions.
- 2) Dimensions: Though the dimension is different from the predicate devices, this difference is insignificant and do not raise any safety or effectiveness problems.
- 3) Light irradiance: For ACNE mode (Red light+ Blue light), its irradiance ($70\text{mW}/\text{cm}^2$) is between that of the primary predicate K242796 ($128\text{mW}/\text{cm}^2$) and predicate device 1 K231555 ($44\text{mW}/\text{cm}^2$). For WRINKLE mode (Red light+ IR light), its irradiance ($124\text{mW}/\text{cm}^2$) is between that of the primary predicate K242796 ($128\text{mW}/\text{cm}^2$) and predicate device 2 K240089 ($35\text{mW}/\text{cm}^2$). For FIRM mode (Yellow light), its irradiance ($20\text{mW}/\text{cm}^2$) is between that of the predicate device 2 K240089 ($35\text{mW}/\text{cm}^2$) and the minimum value of reference device K242151 ($10\text{mW}/\text{cm}^2$). And the treatment time (10min) is the between that of the predicate 2 K240089 (21min) and reference device K242151 (5min). Thus this difference does not raise any safety or effectiveness questions.

Thus the subject device is determined to be substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;

IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems

IEC 60601-2-83: 2019+A1: 2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

The device has been evaluated for biocompatibility as per ISO 10993-1 Fifth edition 2018-08.

The device software has been evaluated as per FDA guidance " Content of Premarket Submissions for Device Software Functions" .

Usability engineering study has been conducted and demonstrated conformance to FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff February 2016".

In order to verify and assure the performance, function and quality of the product, we have conducted performance verification.

The clinical test is not applicable, there's no clinical data.

Based on the above analysis and tests, it can be concluded that the LED Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate devices.