August 29, 2025

Touchbeauty Beauty & Health (shenzhen) Co., Ltd
% Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Room 901, Huafa Center, 889 Pinglu Road, Jing 'an District,
Shanghai, Shanghai 200040
China

Re: K251727
Trade/Device Name: GLAM LED Facial Mask (TB-2386F)
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: June 5, 2025
Received: June 5, 2025

Dear Owen 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 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: 2025.08.29 12:23:12 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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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)*
K251727

Device Name
GLAM LED Facial Mask(TB-2386F)

Indications for Use *(Describe)*

The Red Light is intended to treat full face wrinkles.
The Blue Light is intended to treat mild to moderate inflammatory acne.
The Yellow Light is intended to treat 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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510(k) #: K251727

# 510(k) Summary

Prepared on: 2025-08-28

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | TOUCHBEAUTY BEAUTY & HEALTH (SHENZHEN) CO., LTD. |
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| Correspondent Name | Microkn Medical Technology Service (Shanghai) Co.,Ltd. |
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| Correspondent Contact | Mr. Owen He |
| Correspondent Contact Email | fda@microkn.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | GLAM LED Facial Mask (TB-2386F) |
| Common Name | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Classification Name | Powered Laser Surgical Instrument |
| 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 |
|---|---|---|
| K230293 | TheraFace Mask | OHS&OLP |
| K242700 | Radiant Renewal Skincare Lid | OHS&OLP |

## Device Description Summary

21 CFR 807.92(a)(4)

The GLAM LED light therapy mask is a home use wearable light emitting diode phototherapy device whose purpose is to produce an even, cool, narrow band of light for the treatment of full-face wrinkles and mild to moderate acne of the face.
The outer shell of the mask is manufactured from Polyethylene terephthalate (PET). The inner shell is a clear Polycarbonate (PC). The Light emitting diodes are mounted behind the clear Polycarbonate. The LEDs generate the light. The ear hooks are made of Acrylonitrile butadiene styrene (ABS) and the silicone goggle protect the eyes from LED lights. Unfold the ear hooks and place the mask on your face, the mask will automatically activate the light therapy mode.

The LEDs produce blue, red and yellow light in the visible spectrum (Blue:415nm +/- 10nm, Yellow: 590nm +/-10nm, Red: 625nm +/-10nm.). The device works by emitting the specified wavelengths to treat full face of wrinkles or to treat mild to moderate inflammatory acne.
Press the touch switch on the right ear hook twice to select the light therapy mode you want to use. Each mode operates in a 15-minute cycle. After 15 minutes, the device automatically deactivates the light mode and enters the standby mode.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Red Light is intended to treat full face wrinkles.
The Blue Light is intended to treat mild to moderate inflammatory acne.
The Yellow Light is intended to treat wrinkles.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject and predicate devices share the same indications for use.

## Technological Comparison

21 CFR 807.92(a)(6)

The Subject Device (GLAM LED Facial Mask, Model: TB-2386F) and the legally marketed Predicate Device (TheraFace Mask & Radiant Renewal Skincare Lid) are all Class II powered laser surgical instrument, sharing Product Codes OHS and OLP and falling under regulatory classification 21 CFR 878.4810. These devices all light emitting diode phototherapy device whose purpose is to produce band of light for the treatment of full-face wrinkles and mild to moderate acne of the face.
The power supply of Subject device and Predicate Devices are very similar but not identical, the IEC-60601-1 test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.
Key differences between Subject Device and Predicate Device lie in “Power Density” and “Treatment Time”. The "Standard Dose in Joules" can be calculated as the product of "Power Density" and "Treatment Time." This value may be achieved using either a high power density over a short treatment time or a low power density over a longer treatment time. Although the power density and treatment time of the Subject device and the Predicate devices differ, the resulting standard dose in Joules is comparable and falls within an acceptable deviation range. The device has successfully passed testing in accordance with IEC 60601-2-57, confirming that its performance and safety profile remain unaffected. Thus, these variations do not pose any concerns regarding safety or effectiveness.
Non-clinical testing confirms biocompatibility compliance with ISO 10993-5/-10/-23(no cytotoxicity, sensitization or irritation), electrical safety (IEC 60601-1), EMC (60601-1-2), home use (IEC 60601-1-11) and performance (IEC 60601-2-57 & IEC 62471).
In conclusion, the Subject Device demonstrates substantial equivalence to Predicate in technical principles, clinical functionality, and safety thresholds, satisfying FDA 510(k) substantial equivalence criteria for market authorization.

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

21 CFR 807.92(b)

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following testing items and standards:
Electromagnetic Compatibility (EMC) and Electrical Safety
IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC TR 60601-4-2:2016, Medical electrical equipment- Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-1-11:2020 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 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 60601-2-83: 2023 Medical electrical equipment –Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
Biocompatibility test
For the components in contact with the human body, in vitro cytotoxicity test, skin irritation test, skin sensitization test and systemic toxicity test were conducted according to:
ISO 10993-5:2009, Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

Photobiological Safety
The photobiological safety was tested according to IEC 62471:2006 - Photobiological safety of lamps and lamp systems
Software verification and validation testing
IEC 62304: 2006 (ed. 1.0) Medical Device Software - Software Life Cycle Processes
Clinical Testing
No animal or clinical study is included in this submission
The subject device is substantial equivalence as the predicate devices K230293 and K242700