Septembr 4, 2025

Micowey Medical Equipment (Guangxi) Co., LTD
% Iris Fung
Regulation Manager
SGS-CSTC Standards Technical Services Co., Ltd.
9198 KEZHU Road
SCIENTECH Park Guangzhou Economic & Technology Development D
GuangZhou, Guangdong 510000
China

Re: K251545
Trade/Device Name: Intense Pulsed Light Therapy Device (MMABM-1)
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: ONF
Dated: May 20, 2025
Received: May 20, 2025

Dear Iris Fung:

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: 2025.09.04 18:28:33 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K251545

Device Name
Intense Pulsed Light Therapy Device (MMABM-1)

Indications for Use *(Describe)*
The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions, with treatment filters applied as indicated:
420-1200nm and 515-1200nm: Moderate inflammatory acne vulgaris.
515-1200nm and 560-1200nm: Benign pigmented epidermal lesions (including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)).
515-1200nm and 560-1200nm: Benign cutaneous vascular lesions (including port wine stains, hemangiomas, facial, truncal, and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas, and venous malformations).
590-1200nm, 640-1200nm and 695-1200nm: Permanent hair reduction (long-term stable reduction in the number of hairs regrowing after a treatment regimen).

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) Summary
# # K251545

**Date of the summary prepared: September 4, 2025**

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission with no previous application.

**1. Submitter's Information**

**Sponsor**

- Company Name: Micowey Medical Equipment (Guangxi) Co., LTD
- Address: Room 203, Building B1, Xinghua Community, High-tech Industrial Development Zone, Wanxiu District, Wuzhou City, Guangxi Zhuang Autonomous Region，China

**Application Correspondent**

- Company: SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 9198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Iris
- Tel: 86-13512755282
- Email: jianda-lee@foxmail.com

**2. Subject Device Information**

- Type of 510(k) submission: Traditional
- Common Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
- Trade Name: INTENSE PULSED LIGHT THERAPY DEVICE
- Model: MMABM-1
- Review Panel: General & Plastic Surgery
- Product Code: ONF
- Regulation Number: 878.4810
- Regulation Class: II

**3. Predicate Device Information**

| | **Predicate Device** |
|---|---|
| **Sponsor** | Smedtrum Medical Technology Co., Ltd. |
| **Device Name** | Intense Pulsed Light System (ST-690) |
| **Model** | ST-690 |
| **510(k) Number** | K240482 |
| **Product Code** | ONF |
| **Regulation Number** | 878.4810 |
| **Regulation Class** | II |

**4. Device Description**

Intense Pulsed light (IPL) System is a type of intensive, broadband, coherent light source which has a wavelength spectrum of 420 nm -1200 nm.

There are six optical filters that can be using in this system. With special properties, the IPL System has a wide application in non-ablative therapies based on theory of human skin tissue's selective absorption.

Basic parameters/use conditions/power supply specifications is as follows:

| | |
|---|---|
| light source | Intense Pulsed Light |

| | | | | | | |
|---|---|---|---|---|---|---|
| Filter wavelength nm | 420 | 515 | 560 | 590 | 640 | 695 |
| Wavelength range(nm) | 420-1200 | 515-1200 | 560-1200 | 590-1200 | 640-1200 | 695-1200 |
| Pulse energy J | 1.9 -87.8 | 1.9-236.2 | 1.9-216 | 1.9-202.5 | 1.9-175.5 | 1.9-148.5 |
| Energy density J/cm $^2$ | 5-13 | 5-35 | 5-32 | 5-30 | 5-26 | 5-22 |
| Pulse train width (ms) | 5-500 | 5-200 | | | | |
| Pulse train interval time s | 1s-5s | | | | | |

| | |
|---|---|
| Size of treatment surface | 7mm round, 11mm round, 15mm square, 45mm long and 15mm wide |
| Uniuniformity of the terminal energy output | The relative deviation shall not be greater than ± 20%. |
| Energy output stability | CV≤20% |
| Energy output reproduction | CV≤20% |
| Range of the skin cooling temperature | 15 minutes after powering on, the temperature of the treatment head of the therapeutic device in contact with the skin should be within the range of 0℃ ~ 30 ℃ . |

**5. Intended Use**

The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions, with treatment filters applied as indicated:
420-1200nm and 515-1200nm: Moderate inflammatory acne vulgaris.
515-1200nm and 560-1200nm: Benign pigmented epidermal lesions (including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)).
515-1200nm and 560-1200nm: Benign cutaneous vascular lesions (including port wine stains, hemangiomas, facial, truncal, and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas, and venous malformations).
590-1200nm, 640-1200nm and 695-1200nm: Permanent hair reduction (long-term stable reduction in the number of hairs regrowing after a treatment regimen).

**Test Summary**

The INTENSE PULSED LIGHT THERAPY DEVICE(MMABM-1) was evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

- **Electrical safety test**
  IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  IEC 60601-1-6 Edition 3.2 2020-08, Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
  IEC 60601-1-2 60601-1-2 Edition 4.1, 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 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.

- **Product Life Acceleration (Time Compression) Test**
- **Software verification and validation test**
  FDA “Guidance for Premarket Submissions and for Software Contained in Medical Devices”

Product Life Acceleration (Time Compression) Test Scheme

**6. Comparison to predicate device and conclusion**

The subject device INTENSE PULSED LIGHT THERAPY DEVICE(MMABM-1) is substantially equivalent to the predicated device based on intended use, light source, wavelength and light delivery system. Although the filter，fluence，pulsed energy density，pulsed width，pulsed duration，spot size of subject device have minor difference to the predicate devices, these parameters are similar to the predicate devices. And the subject device comply with IEC/EN 60601-1-6, IEC/EN 60601-1-2, IEC/EN 62471, IEC/EN 60601-2-57 The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. So the differences will not raise any safety or effectiveness issue.

Information for predicate device was obtained from publicly available sources. A technical comparison to the predicate is provided below.

| **Elements of Comparison** | **Subject Device** | **Predicate Device 1** | **Predicate Device 2** | **Verdict** |
|---|---|---|---|---|
| 510(k) Number | | K240482 | K041086 | |
| Device Name | INTENSE PULSED LIGHT THERAPY DEVICE(MMABM-1) | Intense Pulsed Light System | Intense Pulsed Light | |
| Product Code | ONF | ONF | GEX | Same |
| Regulation Number | 21 CFR 878.4810 | 21 CFR 878.4810 | 21 CFR 878.4810 | Same |
| Regulation Class | II | II | II | Same |
| Intended Use | The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions, with treatment filters applied as indicated:<br>420-1200nm and 515-1200nm: Moderate inflammatory acne vulgaris.<br>515-1200nm and 560-1200nm: Benign pigmented epidermal lesions (including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).<br>515-1200nm and 560-1200nm: Benign cutaneous vascular lesions (including port wine stains, hemangiomas, facial, truncal, and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas, and venous malformations).<br>590-1200nm, 640-1200nm and 695-1200nm: Permanent hair reduction (long-term stable reduction in the number of hairs regrowing after a treatment regimen). | The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions: 1. Moderate inflammatory acne vulgaris;<br>2. Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);<br>3. Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations;<br>4. Permanent hair reduction long-term stable reduction in number of hairs re-growing after a treatment regimen. | The StarLuxTM System is intended for treatment of inflammatory acne andf or the treatment of cutaneous lesions, including warts, scars and striae. | Same |
| Light Source | Intense Pulsed light (Xenon Flash Lamp) | Intense Pulsed light (Xenon Flash Lamp) | Intense Pulsed Light | Same |
| Wavelength | 420 – 1200 nm | 420 – 1200 nm | 400-1200nm | Same |
| Light Delivery System | Handpiece | Handpiece | N/A | Same |
| Filter | 420 -1200nm;<br>515 -1200nm;<br>560 -1200nm;<br>590-1200nm;<br>640-1200nm;<br>695-1200nm; | 420 -1200nm: Acne;<br>510 -1200nm: Acne, vascular, pigment;<br>560 -1200nm: Vascular, pigment;<br>610-1200nm: Hair removal;<br>640-1200nm: Hair removal;<br>610-980nm: Hair removal; | N/A | Similar Note 1 |
| Fluence | 420 -1200nm:5-13 J/$cm^2$ ;<br>515 -1200nm: 5-35 J/$cm^2$ ;<br>560 -1200nm: 5-32 J/$cm^2$;<br>590-1200nm: 5-30 J/$cm^2$ ;<br>640-1200nm:5-26 J/$cm^2$ ;<br>695-1200nm: 5-22 J/$cm^2$ ; | 420 -1200nm: 4.1-34.8 J/$cm^2$ ;<br>510 -1200nm: 3.8-31.6 J/$cm^2$ ;<br>560 -1200nm: 3.9-30.2 J/$cm^2$;<br>610-1200nm: 3.9-27.8 J/$cm^2$ ;<br>640-1200nm: 3.3-24.9 J/$cm^2$ ;<br>610-980nm: 3.2-23.3 J/$cm^2$ ; | Up to 50 J/cm2 | Similar Note 2 |

| Elements of Comparison | Subject Device | Predicate Device 1 | Predicate Device 2 | Verdict |
|---|---|---|---|---|
| Pulsed Energy Density | 5~35 J/ $cm^2$ | 4.1~35 J/ $cm^2$ (10~50 Level) | N/A | Different Note 3 |
| Pulsed width | 420 -1200nm:5-500ms;<br>515 -1200nm:5-200ms;<br>560 -1200nm:5-200ms;<br>590-1200nm:5-200ms;<br>640-1200nm:5-200ms;<br>695-1200nm:5-200ms; | 5~20 ms | 1-500 ms | Different Note 4 |
| Pulsed Duration | 1-5s | 5~50 ms | N/A | Different Note 5 |
| Spot Size | 7mm round, 11mm round, 15mm square, 45mm long and 15mm wide | 12 mm × 35 mm & 15 mm × 50 mm | 16x46mm, 12x28mm, 10 x 15 mm | Different Note 6 |
| Appearance | 126 | Height 451 mm | N/A | Different Note 7 |
| | 486 | Width 468 mm | N/A | Different Note 7 |
| | 527 | Depth 630 mm | N/A | Different Note 7 |

**7.Summary for clinical test**

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.Conclusion**

Based on the above performance as documented in this application, INTENSE PULSED LIGHT THERAPY DEVICE(MMABM-1) was found to have a safety and effectiveness profile that is similar to the predicate devices. Thus, the subject device is substantially equivalent to the predicate devices.