U.S. FOOD & DRUG ADMINISTRATION

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July 3, 2025

Medusa (Guangxi)Medical Devices Co., Ltd.
℅ Candice Qiu
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K243123
Trade/Device Name: IPL Treatment Device (MDSQMC-01)
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: July 3, 2025
Received: July 3, 2025

Dear Candice Qiu:

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,

MARK MACIOS -S
Digitally signed by MARK MACIOS -S
Date: 2025.07.03 11:56:25 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243123

Device Name

IPL Treatment Device (MDSQMC-01)

Indications for Use *(Describe)*

The IPL Treatment Device (Model: MDSQMC-01) is intended for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.
Mild to moderate inflammatory Acne (Acne vulgaris)
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9,and 12 months after the completion of 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.

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510(k) Summary of K243123

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

MEDUSA (Guangxi) Medical Devices Co., Ltd.
Address: Room 602, Building 1, Intersection of Renhou Road and Weier Road(Northwest side), Yulin Traditional Chinese Medicine Health Industrial Park, Renhou Town, YuLin City, Guangdong Province, China

Contact Person: Zhanai Chen
Title: General Manager
Tel: +86 13825005622
Email: mds13825005622@126.com

Preparation date: 07/03/2025

II. Device

Name of Device: IPL Treatment Device
Model(s): MDSQMC-01
Regulation Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Regulatory Class: II
Product Code: ONF
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shangdong Huamei Technology Co., Ltd.	The Intense Pulsed Light Treatment System, (Model: HM-IPL-B8)	K230816	April 21, 2023

Reference device:

Manufacturer	Reference Device	510(k) Number	Approval Date
Beijing Superlaser Technology Co., Ltd.	IPL Treatment Device, (Model: AAD Dual Light)	K192519	November 6, 2019
Lumenis Ltd.	Stellar M22 for Intense Pulsed Light (IPL) and Laser system	K193500	January 16, 2020

IV. Device Description

The IPL Treatment Device is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 400nm-1200nm, Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.
IPL Systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.
Based on this, the IPL Treatment Device (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, and reduction of benign pigmented lesions and benign vascular lesions.

V. Indications for Use

The IPL Treatment Device (Model: MDSQMC-01) is intended for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.
Mild to moderate inflammatory Acne (Acne vulgaris).

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9,and 12 months after the completion of a treatment regimen.

VI. Materials

Component name	Body Contact Category	Contact Duration
IPL Treatment Device (Handle, Light guide, Expertfilter)	Surface-contacting device: Intact skin	Less than 24 hours

VII.Comparison of Technological Characteristics With the Predicate Device

The IPL Treatment Device has the same intended use, mode of action and similar operational characteristics as the predicate device. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use. Therefore, the IPL Treatment Device may be found substantially equivalent to its predicate device and reference devices.

IPL Treatment Device is compared with the following Predicate Device and Reference Devices in terms of intended use, design, material, specifications, and performance:

Comparison Elements	Subject Device	Predicate Device	Reference devices 1	Reference devices 2	Remark
510(k) Number	Pending	K230816	K192519	K193500	/
Trade name	IPL Treatment Device, (Model: MDSQMC-01)	The Intense Pulsed Light Treatment System, (Model: HM-IPL-B8)	Multi-modality workstation, (Model: AAD Dual Light)	Stellar M22 for Intense Pulsed Light (IPL) and Laser system	/

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference devices 1**	**Reference devices 2**	**Remark**
Manufacturer	MEDUSA (Guangxi) Medical Devices Co., Ltd.	Shangdong Huamei Technology Co., Ltd.	Beijing Superlaser Technology Co., Ltd.	Lumenis Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	ONF	ONF	ONF	GEX, ONF, ONG	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	The IPL Treatment Device (Model: MDSQMC-01) is intended for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions. Mild to moderate inflammatory Acne (Acne vulgaris). Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9,and 12	The Intense Pulsed Light Treatment System (Model:HM-IPL-B8) are indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9,and 12 months after the completion of a treatment regimen.	The Multi-modality workstation (inclusive of the andpiece used to deliver ulsed-light energy) is indicated for se in surgical and aesthetic pplications in permanent hair emoval, reduction of benign igmented lesions and benign ascular lesions. Permanent hair reduction is defined s the long-term, stable reduction in he number of hairs regrowing when easured at 6, 9, and 12 months fter the completion of a	The Lumenis Stellar M22 has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows: The Stellar Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:	Same

Comparison Elements	Subject Device	Predicate Device	Reference devices 1	Reference devices 2	Remark
	months after the completion of a treatment regimen.		treatment egimen.	o Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles) o Cutaneous lesions, including warts, scars and striae o Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations o Removal of unwanted hair and to effect stable long term, or	

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference devices 1**	**Reference devices 2**	**Remark**
				permanent* hair reduction in skin types 1-V through selective targeting of melanin in hair follicles o Mild to moderate inflammatory Acne (Acne vulgaris)	
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Wavelength	Acne (400nm-600nm, 800-1200nm), 515nm-1200nm, 560nm-1200nm, 590nm,-1200nm, 615nm-1200nm, 640-1200nm, 695-1200nm	430-1200nm, 530-1200nm, 640-1200nm Optional: 480nm-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750nm-1200nm	520-650nm, 800~1200nm, 540-800nm, 640-1200nm	400-1200 nm	Different **Note 1**
Energy density	10-35J/cm^2	10-50J/cm^2±20%error	1-50J/cm^2	Up to 35 or 56 J/cm$_2$, upon tip size	Similar **Note 2**
Pulse Width	3-20ms	1-20ms±10%error	1-25ms	Unknown	Similar **Note 3**
Max. Power	2400VA	2000W	3500VA	Unknown	Similar **Note 4**

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference devices 1**	**Reference devices 2**	**Remark**
Spot size	10mmx45mm	15mmx50mm; 80mmx40mm±20%error	Small: 40 x 12 mm Large: 46 x 16mm Ex-Large: 60 x 20mm	8x15 mm (1.20 cm^2)	Similar **Note 5**
Safety Comparison					
Power supply	AC100~240V, 50/60Hz	110V±10% 60Hz	110V, 60Hz or 230V, 50Hz	Unknown	Different **Note 6**
Electrical Safety	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	IEC 60601-1	Same
EMC	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	IEC 60601-1-2	Same
Patient Contact Material	Handpiece	Handpiece (Sapphire Crystal)	Handpiece	Handpiece has three (3) Sapphire Cool Light Guides	Same
Biocompatibility					
Cytotoxicity	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)		Same
Irritation	Applied sample did not induce irritation to skin. (ISO 10993 -23)	Applied sample did not induce irritation to skin. (ISO 10993 -10)	Applied sample did not induce irritation to skin. (ISO 10993 -10)	Unknown	Same
Sensitization	The test article showed no signification evidence of causing skin	The test article showed no signification evidence of causing skin	The test article showed no signification evidence of causing	Unknown	Same

Comparison Elements	Subject Device	Predicate Device	Reference devices 1	Reference devices 2	Remark
	sensitization in the guinea pig. (ISO 10993-10)	sensitization in the guinea pig. (ISO 10993-10)	skin sensitization in the guinea pig. (ISO 10993-10)		

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the IPL Hair Removal Device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices -Part 5: Tests 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 skin irritation.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2: 2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility.
- IEC 60601-1: 2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC60601-2-57: 2011, Medical electrical equipment - Part 2-57: Particular requirements for thebasic safety and essential performance of non-laser light source equipment intended for therapeutic.diagnostic, monitoring and cosmetic/aesthetic use.

3) Eye Safety

- IEC 62471: 2006, Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***Basic Documentation risk level*** was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

5) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

IX. Conclusions

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