August 21, 2024

Guangzhou Ciellulu Photoelectric Technology Co., Ltd
% Riley Chen
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K240314
Trade/Device Name: Mula (k2-a1)
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: February 1, 2024
Received: February 2, 2024

Dear Riley Chen:

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.

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: 2024.08.21 11:54:52 -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)*
K240314

Device Name
MULA (K2-A1)

Indications for Use *(Describe)*
MULA is intended for aesthetic and dermatological skin procedure applications by using multi-filtered Intense Pulsed Light/ Dye Pulsed Light. Intended Use for the 400-1200nm (including 8 filters) Light:
1) Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
2) Cutaneous lesions, including warts, scars and striae.
3) Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, facial and leg veins and venous malformations.
4) Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles.
5) Mild to moderate inflammatory Acne (Acne vulgaris)

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

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

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

I. Submitter

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Date of preparation: 2024-08-19

II. Device

Name of Device: MULA (K2-A1)
Common or Usual Name: Powered Light Based Non-Laser Surgical Instrument
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONF
Regulation Number: 21 CFR 878.4810

III. Predicate Device & Reference Device

Predicate devices:

510(k) Number	Predicate Device	Product code
K193500	Stellar M22 for Intense Pulsed Light (IPL) and Laser System	GEX, ONF, ONG
K193072	Lucent : IPL	ONF

IV. Device Description

The MULA is a multi-application, multi-technology system, with an IPL&DPL handpiece and 8 different filters: 515nm/ 560nm/ 590m/ 615nm/ 640nm/ 695nm/ Acne Filter (Notch filter 400-600 and 800-1200) and Vascular Filter (Notch filter 530-650 & 900-1200), and it also equips two precision treatment heads (38x10mm and 8mm diameter).

V. Indications for Use

MULA is intended for aesthetic and dermatological skin procedure applications by using multi-filtered Intense Pulsed Light/ Dye Pulsed Light. Intended Use for the 400-1200nm (including 8 filters) Light:

1) Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
2) Cutaneous lesions, including warts, scars and striae.
3) Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, facial and leg veins and venous malformations.
4) Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles.
5) Mild to moderate inflammatory Acne (Acne vulgaris)

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

Comparison of Indications for Use: The indications for use of the subject device is comparable to the indications for use of the predicate devices.

VI. Comparison of Technological Characteristics

Device & Predicate Device(s):	K240314 (Subject)	K193500 (Predicate)	K193072 (Predicate)
General Device Characteristics			
Light Source	Intense Pulsed Light Dye-pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Wavelength (nm)	400-1200	400-1200	400-1200
Filters	515-950nm 560-950nm 590-950nm 615-950nm 640-950nm 695-950nm Acne (400-600 & 800-1200) Vascular (530-650 & 900-1200)	515/560/590/615/640/695/755 Acne (400-600 & 800-1200) Vascular (530-650 & 900-1200)	430-980nm 515-980nm 560-980nm 585-980nm 640-980nm 700-980nm
Pulse duration (ms)	1-30	20	3-35
Pulse interval (ms)	1-99	5-150	0-50

Pulse Sequences	1, 2, or 3 sub-pulses	1, 2, or 3 sub-pulses	1, 2, 3, toning (ST Mode: 430/515/560/585/640) 1, 2, 3 (HR mode: 700)
Spot size (cm^2)	14mm X 38mm (5.32 cm^2) 38 mm X 10 mm (3.8 cm^2) 8 mm round (0.5 cm^2)	8 mm X 15 mm (1.2 cm^2) 15 mm X 35 mm (5.25 cm^2) 6 mm round (0.3 cm^2)	15 mm X 40 mm
Maximum Fluence (J/cm^2)	2-40	35 (@ 8 X 15 mm^2, 15 X 35 mm^2) 56 (@ 6mm round)	6-40
Repetition Rate (Hz)	1-5	1	Unknown
Contact Sapphire Cooling T (^0C)	5-20	0-10 (Rectangular) 0-15 (Round)	Range:-5 to 20 (Chiller @ 15)

Note: Not all combinations of technical parameters are permissible in the subject device.

VII. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- 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 irritation
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-57 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 62471 Photobiological safety of lamps and lamp systems

VIII. Clinical Testing

Not applicable.

IX. Conclusions

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