July 25, 2024

Dongguan Hunter Electronic Technology Co., Ltd.
% Riley Chen
Official Correspondent
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K241203
Trade/Device Name: PMD Clean Redvolution (4005-moab-NA, 4005-moab-INT, 4005-pepper-NA, 4005-pepper-INT, 4005-cream-NA, 4005-cream-INT, 4005-twilight-NA , 4005-twilight-INT, 4005-grey-NA, 4005-grey- INT)
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
Dated: April 30, 2024
Received: April 30, 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: 2024.07.25 21:25:28 -04'00'

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)*

K241203

Device Name

PMD Clean Redvolution (4005-moab-NA, 4005-moab-INT, 4005-pepper-NA, 4005-pepper-INT, 4005-cream-NA, 4005-cream-INT, 4005-twilight-NA , 4005-twilight-INT, 4005-grey-NA, 4005-grey-INT)

Indications for Use *(Describe)*

The PMD Clean Redvolution (All 4005 models) is a hand-held device for over-the counter aesthetic purposes. The red light is intended for the use in treating wrinkles on the face.

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 K241203

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Dongguan Hunter Electronic Technology Co., Ltd.
Address:	Room 301, Building 6, 74 Qiaodong Road, Tangxia Town, Dongguan City, Guangdong, P.R. China
Contact person:	Hunter Ye
Phone number:	+86 13554760590
Email:	13554760590@139.com
Date of summary prepared:	2024-7-25

(2) Proprietary name of the device

Trade name/model:	PMD Clean Redvolution (4005-moab-NA, 4005-moab-INT, 4005-pepper-NA, 4005-pepper-INT, 4005-cream-NA, 4005-cream-INT, 4005-twilight-NA , 4005-twilight-INT, 4005-grey-NA, 4005-grey-INT)
Common name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification	Light Based Over The Counter Wrinkle Reduction
Regulation number:	21 CFR 878.4810
Product code:	OHS
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(3) Predicate & Reference device

Predicate	**Predicate Trade Name**	**Produce code**
K202055	Looper (Model: ZX-579S)	OHS , OLP
Reference	**Reference Trade Name**	**Produce code**
K162098	LED Phototherapy Device. Model:PL-120	OHS , OLP

(4) Description/ Design of device:

PMD Clean Redvolution adopts light emitting diodes (LED) in the red (630nm±5nm) spectrum to irradiate on the face for the treatment of facial wrinkles. PMD Clean Redvolution adopts handheld design, LEDs are contained in the red light therapy treatment window, and on its reverse side, the soft silicone bristles can be used to clean the face before the red light treatment. The product is

provided with internal battery and it can be charged by external adaptor. To prevent irradiation of LED lights to eyes during the treatment, PMD Clean Redvolution is equipped with goggles which blocks light energy from LEDs.

PMD Clean Redvolution includes 10 models, the only difference between these models is the enclosure color.

(5) Indications for use:

The PMD Clean Redvolution (All 4005 models) is a hand-held device for over-the counter aesthetic purposes. The red light is intended for the use in treating wrinkles on the face.

(6) Technological characteristics and substantial equivalence:

Item	Subject device	Predicate device	Reference device	Remark
Trade name and model	PMD Clean Redvolution Model: 4005-moab-NA, 4005-moab-INT, 4005-pepper-NA, 4005-pepper-INT, 4005-cream-NA, 4005-cream-INT, 4005-twilight-NA, 4005-twilight-INT, 4005-grey-NA, 4005-grey-INT,	Looper (Model: ZX-579S)	LED Phototherapy Device. Model:PL-120	/
510 (k) number	Pending	K202055	K162098	/
Manufacturer	Dongguan Hunter Electronic Technology Co., Ltd.	Heat In A Click	Li-Tek Electronics Technologies	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Classification name	Light Based Over The Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based Over the Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Same
Product code	OHS	OLP, OHS	OLP, OHS	Same
Class	II	II	II	Same
Indications for use/ Intended use	The PMD Clean Redvolution (All 4005 models) is a hand-held	Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic	The red light is intended for the treatment of periorbital	Same

	device for over-the counter aesthetic purposes. The red light is intended for the use in treating wrinkles on the face.	purposes. The Photon mode red light is indicated for the use in treating wrinkles on the face, and the blue light is indicated for the treatment of the mild to moderate inflammatory acne.	wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	
Location for use	Face	Entire Face	Face	Same
OTC or prescription	OTC	OTC	OTC	Same
Basic unit characteristics				
Design	Hand-held device	Hand-held device	Hand-held device	Same
Power supply	3.7V 1000mAh Li-ion Battery	DC 3.7V 1000mA Li battery	3.7V 1050mAh Li battery	Same
Weight	135g	230g	150g	Different
Dimensions	175.2 * 56 * 37mm	234.5mm x 30mm x 46mm	187*65*51mm	Different
Irradiation area	11cm² (±5%)	12cm² ±10%	30cm²±5%	Similar
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same
Sterilization	Not required	No publicity	Not required	Same
Output specifications				
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	Red: 630nm±5nm	Red: 630±10nm Blue: 415±10nm	Red: 630 ± 3nm Blue: 415 ± 3nm	Same
Irradiance	Red: 70mW/cm²±10%	Red: 55mW/cm²±10% Blue: 48mW/cm²±10%	Red: 80mW/cm²±10% Blue: 65mW/cm²±10%	Similar
Additional features				
Treatment duration	3 minutes for each part	3 minutes per target area	3 minutes per target area	Same
Materials of skin-contacting components	Silicone, plastic, glass	ABS Plastic & Stainless Steel	ABS plastic	Different
Environment for Operating	Temperature: 5-40℃ Humidity: 10-80%RH Atmospheric pressure: 700hPa-1060hPa	Temperature: 5-35℃ Humidity: 10-80%RH Atmospheric pressure: 700hPa-1060hPa	Temperature: 5 ~ 40℃ Humidity: 10%-80% Atmospheric pressure: 700hPa-1060hPa	Same
Biocompatibility feature	Comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23	Comply with ISO 10993-5:2009 and ISO 10993-10: 2010	ABS plastic in hand hold part can be considered safety	Same

Electrical safety	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	60601-1-2	Same
Photobiological safety	IEC 62471	Unknown	IEC 62471	Same

(7) Non-clinical and/or Clinical Tests Summary & Conclusions

Non-clinical testings have been conducted to verify that the PMD Clean Redvolution meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- IEC 60601-1, Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Edition 4.1 2020-09 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 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 62471, First edition 2006-07 Photobiological safety of lamps and lamp systems
- IEC 62133-2, Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes -Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

The device has been tested for biocompatibility, it complies with the following standards:

- ISO 10993-5, Third edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10, Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23, First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

We have also conducted:

Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

Clinical test is not applicable, so there is no clinical data.

Based on the above analysis and non-clinical tests performed, the subject device and predicate device have the same indications for use and technological characteristics, it can be concluded that the subject device is as safe, as effective and performs as well as the predicate device.