October 27, 2023

Dongguan Hunter Electronic Technology Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rn 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K230490
Trade/Device Name: PMD Clean Acne, Model: 4004-CABLUE-NA, 4004-GREY-NA, 4004-YELLOW-NA, 4004-PSTO-NA, 4004-LPUR-NA, 4004-CABLUE-NA-INT, 4004-GREY-INT, 4004-YELLOW-INT, 4004-PSTO-INT, 4004-LPUR-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: OLP
Dated: February 23, 2023
Received: February 23, 2023

Dear Tracy Che:

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
2023.10.27 00:05:32 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230490

Device Name
pmd clean acne, Model: 4004-CABLUE-NA, 4004-GREY-NA, 4004-YELLOW-NA, 4004-PSTO-NA, 4004-LPUR-NA, 4004-CABLUE-NA-INT, 4004-GREY-INT, 4004-YELLOW-INT, 4004-PSTO-INT, 4004-LPUR-INT

Indications for Use *(Describe)*
The pmd clean acne is intended for over-the-counter use to treat mild to moderate inflammatory acne.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary K230490

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:	13554760590
Email:	13554760590@139.com
Date of summary prepared:	2023-9-22

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	pmd clean acne, Model: 4004-CABLUE-NA, 4004-GREY-NA, 4004-YELLOW-NA, 4004-PSTO-NA, 4004-LPUR-NA, 4004-CABLUE-NA-INT, 4004-GREY-INT, 4004-YELLOW-INT, 4004-PSTO-INT, 4004-LPUR-INT
Common name:	Over-The-Counter Powered Light Based Laser For Acne
Regulation number:	21 CFR 878.4810
Product code:	OLP
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate device

Sponsor	Li-Tek Electronics Technologies
Device Name and Model	LED Phototherapy Device. Model:PL-120
510(k) Number	K162098
Product Code	OLP, OHS
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

The pmd clean acne adopts light emitting diodes (LED) in the blue (415nm ± 5nm) spectrum to

irradiate on the face to realize its therapeutic effect. The pmd clean acne adopts handheld design, LEDs are contained in the blue light treatment window, and on its reverse side, the soft silicone bristols can be used to clean the face before the blue 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 acne is equipped with goggles which blocks light energy from LEDs.

(6) Indications for use:

The pmd clean acne is intended for over-the-counter use to treat mild to moderate inflammatory acne.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
pmd clean acne	Silicone, plastic, glass	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Subject device	Predicate device	Remark
Trade name	pmd clean acne, Model: 4004-CABLUE-NA, 4004-GREY-NA, 4004-YELLOW-NA, 4004-PSTO-NA, 4004-LPUR-NA, 4004-CABLUE-NA-INT, 4004-GREY-INT, 4004-YELLOW-INT, 4004-PSTO-INT, 4004-LPUR-INT	LED Phototherapy Device. Model:PL-120	/
510 (k) number	Pending	K162098	/
Manufacturer	Dongguan Hunter Electronic Technology Co., Ltd.	Li-Tek Electronics Technologies	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Classification name	Over-The-Counter Powered Light Based Laser For Acne	Over-The-Counter Powered Light Based Laser For Acne	Same

Product code	OLP	OLP, OHS	Same
Class	II	II	Same
Indications for use/ Intended use	The pmd clean acne is intended for over-the- counter use to treat mild to moderate inflammatory acne.	The red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	Similar, the indications for use of the subject device is within that of the predicate device.
Location for use	Face	Face	Same
OTC or prescription	OTC	OTC	Same
Basic unit characteristics			
Power supply	3.7V 1000mAh Li-ion Battery	3.7V 1050mAh Li battery	Similar
Weight	135g	150g	Different
Dimensions	175.2 * 56 * 37mm	187*65*51mm	Different
Irradiation area	11.04cm²±5%	30cm²±5%	Different
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Same
Sterilization	Not required	Not required	Same
Output specifications			
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	Blue: 415nm±5nm	Red: 630 ± 3nm, Blue: 415 ± 3nm	Similar
Irradiance	Blue: 70mW/cm²±10%	Red: 80mW/cm^2±10% Blue: 65mW/cm^2±10%	Similar
Additional features			
Treatment duration	3 minutes for each part	3 minutes per target area	Same
Materials of skin-contacting components	Silicone, plastic, glass	ABS plastic	Different
Work environment	Temperature: 5-30℃ Humidity: 10-80%RH Atmospheric pressure: 700hPa-1060hPa	Temperature: 5 ~ 40℃ Humidity: 10%-80% Atmospheric pressure: 700hPa-1060hPa	Similar
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5, ISO 10993-10 and ISO 10993-23	ABS plastic in hand hold part can be considered safety	Similar

Electrical safety	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	Same
Photobiological safety	IEC 62471	IEC 62471	Same

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the pmd clean acne 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:

- ANSI AAMI ES 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 60601-1-11, 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, 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, Photobiological safety of lamps and lamp systems
- IEC 62133-2, 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, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23, 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"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device pmd clean acne is as safe, as effective, and performs as well as the legally marketed predicate device, K162098, LED Phototherapy Device.