November 14, 2023

Premier North America Inc.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 602, No. 19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K232656
Trade/Device Name: BLU TOTALE (Model: ENEOB852)
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: August 24, 2023
Received: August 31, 2023

Dear Doris Dong:

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
Tanisha L. Hithe -S
2023.11.14
12:36:32 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K232656

Device Name
BLU TOTALE (Model: ENEOB852)

Indications for Use *(Describe)*
BLU TOTALE is an over the counter phototherapy device for use in dermatology for the treatment of mild to moderate 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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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K232656
Date:	November 2, 2023
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	Premier North America Inc. 3301 SW 42ND ST., FORT LAUDERDALE, FL 33312-6828, USA Tel: +1-855-360-0650 Email: customerservice@premierna.com Web: www.premierdeadsea-usa.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	BLU TOTALE
Model:	ENEOB852
Classification Name:	Over-The-Counter Powered Light Based Laser For Acne (OLP)
Regulation Number:	21 CFR 878.4810
Product Code:	OLP
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	BLU TOTALE is a battery-operated device that uses low power light spectrum at blue LED, at wavelength of 415 ±15nm emitting optical power in a uniform distribution with no hot spots. It is a hand held light emitting diode (LED) device for the treatment of acne designed for home-use.
Indications for use:	BLU TOTALE is an over the counter phototherapy device for use in dermatology for the treatment of mild to moderate acne.

3. Predicate Device Identification

Predicate 510(k) Number:	K172555
Marketing clearance date:	05/01/2018
Product name:	Sapphire
Manufacturer:	Omm Imports, Inc. d/b/a Zero Gravity

4. Substantial Equivalence to Predicate device

	New Device	Predicate Device	Remark
510(k) Number	To be assigned	K172555	--
Proprietary Name	BLU TOTALE	Sapphire	--
Model	ENEOB852	Not publicly available	--
Owner	Premier North America Inc.	Omm Imports, Inc. d/b/a Zero Gravity	--
Product Code	OLP	OLP	Same
Classification	II	II	Same
Indications for use	BLU TOTALE is an over the counter phototherapy device for use in dermatology for the treatment of mild to moderate acne.	The SAPPHIRE is an over – the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use in the treatment of mild to moderate inflammatory acne.	Same
Type	Hand-held	Hand-held	Same
Materials	Rigid ABS and stainless steel	Rigid ABS and stainless steel	Same
Target Population	Individuals with mild to moderate acne on the face	Individuals with mild to moderate acne	Same
Anatomical Sites	Entire Face	Entire Face	Same
Light source	Light emitting diode (LED)	Light emitting diode (LED)	Same
Light spectrum region	Blue light	Blue light	Same
Wavelengths	415±15nm	415±5nm	Similar
Waveform	Constant	Constant	Same
Visible light LEDs	Yes	Yes	Same
Energy source	24 pcs LEDs over 15cm^2	Not publicly available	Similar
Energy density	50mW/cm^2	50mW/cm^2	Same
Initial treatment course	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)	Same
Power supply	Lithium battery	Lithium battery	Same

5. Non-clinical Testing

The BLU TOTALE has been evaluated the safety and performance by lab bench testing and conforms to the following international consensus standards:

Electrical safety:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)

EMC:

- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Additional safety testing:

- IEC 60601-1-11 Edition 2.0 2015-01 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems;

Biocompatibility testing:

- 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;
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Performance testing:

- Pyrogen Testing
- Skin Temperature Testing
- LED Wavelength And Power Density Testing

6. Conclusions

The conclusion drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K172555.