January 6, 2022

Premier North America Inc.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K213841
Trade/Device Name: ENEO TOTALE (Model: ENEOT947)
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: October 11, 2021
Received: December 9, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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)*
K213841

Device Name
ENEO TOTALE

Indications for Use *(Describe)*
ENEO TOTALE is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K213841
Date:	November 24, 2021
Type of 510(k) Submission:	Special
Basis for 510(k) Submission:	Change to existing 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 903, 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:	ENEO TOTALE
Model:	ENEOT947
Common Name:	Red/IR Light Therapy Device
Classification Name:	Light Based Over The Counter Wrinkle Reduction
Regulation Number:	21 CFR 878.4810
Product Code:	OHS
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	ENEO TOTALE is a battery-operated device that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±5nm, 830 ±5nm 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 periorbital wrinkles designed for home-use.
Indications for use:	ENEO TOTALE is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

3. Predicate Device:

Avologi ENEO	K181659

4. Substantial Equivalence to Predicate device:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

Table 1-

	New Device	**Predicate Device**	**Remark**
510(k) Number	K213841	K181659	---
Proprietary Name	ENEO TOTALE	Avologi ENEO	---
Product Code	OHS	OHS	Same
Class	2	2	Same
Applicant	Premier North America Inc	Premier North America Inc	Same
Indications for use	ENEO TOTALE is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	Avologi ENEO is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	Same
Handheld	Yes	Yes	Same
Target Population	Individuals with periorbital lines and wrinkles	Individuals with periorbital lines and wrinkles	Same
Location for use	OTC	OTC	Same
Materials	ABS and stainless steel	ABS and stainless steel	Same
Visible LCD	Yes	No	Same Note 1
Wavelengths	633 ±5nm, 830 ±5nm	633 ±5nm, 830 ±5nm	Same
Waveform	Constant	Constant	Same
Light source	Light emitting diode(LED)	Light emitting diode(LED)	Same
Visible light LEDs	Yes	Yes	Same
Energy Source	24 LEDs(12pcs 633nm LEDs+ 12pcs 830nm LEDs) over 15cm^2	24 LEDs(12pcs 633nm LEDs+ 12pcs 830nm LEDs) over 15cm^2	Same
Energy Level	69mW/cm^2 for 633nm 56mW/cm^2 for 830nm	69mW/cm^2 for 633nm 55mW/cm^2 for 830nm	Same Note 2
Therapeutic temperature range	41±2°C / 105.8±35.6°F	41±2°C / 105.8±35.6°F	Same
Power supply	Adaptor:100~240V AC 50/60Hz 2.4A Lithium battery: 3.75Vdc, 3000 mAh	Adaptor:100~240V AC 50/60Hz 2.4A Lithium battery: 3.75Vdc, 3000 mAh	Same
Handpiece charging method	In Charging cradle	In Charging cradle	Same
Initial treatment course	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each	Same

	(5-7 minutes on each treatment zone).	time (5-7 minutes on each treatment zone).	
Maintenance regime	Once a week for 15-20 minutes	Once a week for 15-20 minutes	Same
Anatomical Sites	Periorbital Area	Periorbital Area	Same
Standard meet	IEC60601-1 IEC60601-1-2 IEC60601-1-11 IEC62471	IEC60601-1 IEC60601-1-2 IEC60601-1-11 IEC62471	Same
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Same
Note 1: The proposed device has a small LCD display while predicate device do not have. The LCD display of the proposed device is used for improved battery level indication and to display treatment time. Based on this change, the proposed device has been re-evaluated for IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11,IEC 62471 and software validation report, and the test results indicate that this difference does not raise any new safety and effectiveness issues. Note 2: The energy density of the proposed device for 633nm is approximate to the predicate device. Subtle differences will not raise any new issues of safety or effectiveness.			

5. Non-clinical Testing:

The conclusions drawn from the non-clinical testing below demonstrate that the ENEO TOTALE is substantially equivalent to the predicate devices K181659. The ENEO TOTALE has been tested and conforms to 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 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

Additional safety testing:

- IEC60601-1-11 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 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 10993-1:2009/(R) 2013, Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process. (Biocompatibility)
- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For

Irritation And Skin Sensitization. (Biocompatibility)

The ENEO TOTALE has been tested to ensure the device meets specifications:

Performance testing

- Software Validation Testing

The ENEO TOTALE's software was tested and validated in accordance with FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."

6. Conclusion

The conclusion drawn from the substantial equivalence table is that the new device is substantially equivalent to the predicate device and presents no new questions of safety and effectiveness.