July 26, 2018

Premier North America Inc.
% Doris Dong
Consultant
Shanghai CV Technology Co., Ltd.
Room 903 of Dongbao Building
No. 19 Dongbao Road, Songjiang Area
Shanghai, 201613 Cn

Re: K181659
Trade/Device Name: Avologi ENEO
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: June 13, 2018
Received: June 28, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181659

Device Name

Avologi ENEO

Indications for Use *(Describe)*

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.

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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Premier North America Inc.
3301 SW 42ND ST., FORT LAUDERDALE, FL 33312-6828, USA

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K_ _ _ _ _ _
Date:	June 13th, 2018
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Applicant / Owner:	Premier North America Inc. 3301 SW 42ND ST., FORT LAUDERDALE, FL 33312-6828, USA
Manufacturer:	Premier Dead Sea Cosmetic Laboratories Ltd. Shaked Street No. 21 Shoham, Israe
Submitter / Contact:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris_d@126.com Tel: 86 21-31261348

2. Device Description:

Proprietary Name:	Avologi ENEO
Common Name:	Light Emitting Diode (LED) device
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	OHS
Device Class:	II
Regulation Number:	21 CFR 878.4810
Review Panel:	General & Plastic Surgery
Indications for use:	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.
Device Description:	Avologi ENEO 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.

3. Predicate Device Identification

K110301--Silk'n FX (Home Skinovations Ltd.) -- August 19, 2011

K152332--Perfectio LED infrared device (OMM IMPORTS INC DBA ZERO GRAVITY) -- January 27, 2015

4. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

* AAMI / ANSI 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 60601-1-2 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
* 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

The patient contact materials in Avologi ENEO are the body housing material of ABS and the head housing material of Stainless steel 304. Both the two materials were tested and found to meet the biocompatibility standards of:
* ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
* ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, and
* ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

5. Substantial Equivalent Based on Assessment of Clinical Performance Data:
Clinical data was not including in this submission.

6. Substantially Equivalent Comparison Conclusion

	New Device	**Predicate Device**	**Predicate Device**
510(k) Number:	------	K152332	K110301
Product Code:	OHS	OHS	OHS
Proprietary Name:	Avologi ENEO	Perfectio LED infrared device	Silk'n FX
Manufacturer:	Premier Dead Sea Cosmetic Laboratories Ltd.	OMM IMPORTS INC DBA ZERO GRAVITY	Home Skinovations Ltd.
Indications for use:	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.	Perfectio LED infrared device 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.	Silkn FX 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.
Product pictures:			
Handheld	Yes	Yes	Yes

Materials	ABS and stainless steel	ABS and stainless steel	ABS and stainless steel
product composition	the CHARGING CRADLE, an APPLICATOR and a POWER SUPPLY	the BASE UNIT, an APPLICATOR and an ADAPTER	the BASE UNIT, an APPLICATOR and an ADAPTER
Wavelengths	633 ±5nm, 830 ±5nm	633 ±5nm, 830 ±5nm	633 ±5nm, 830 ±5nm
Waveform	Constant	Constant	Constant
Light source	Light emitting diode(LED)	Light emitting diode(LED)	Light emitting diode(LED)
light spectrum region	red and IR region of the spectrum	red and IR region of the spectrum	red and IR region of the spectrum
Energy source	24 pcs LEDs(12pcs 633nm LEDs+ 12pcs 830nm LEDs) over 15cm^2	25 pcs LEDs(12pcs 633nm LEDs+ 13pcs 830nm LEDs) over 17 cm^2	24 LEDs(12pcs 633nm LEDs+ 12pcs 830nm LEDs) over 12 cm^2
Energy density	69mW/cm^2 for 633nm 55mW/cm^2 for 830nm	70mW/cm^2 for 633nm 55mW/cm^2 for 830nm	70mW/cm^2 for 633nm 55mW/cm^2 for 830nm
Therapeutic temperature range	41±2°C / 105.8±35.6°F	41±2°C / 105.8±35.6°F	41°C
Power supply	Adaptor:100~240V AC 50/60Hz 2.4A Lithium battery: 3.6Vdc, 2600 mAh	Adaptor:100~240V AC 50/60Hz 0.2A Lithium battery: 7.4Vd.c. 900mAh	Adaptor:100~240V AC 50/60Hz 0.4A Lithium battery: 2x3.7V, 750±50mAh
Handpiece charging method	In CHARGING CRADLE	In Base Unit	In Base Unit
Initial treatment course	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time (5-7 minutes on each treatment zone).	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).	Week 1, first day (day 1): 20 min IR light on each area Two days later (day 3): 20 min RED light on each area Week 2, first day (day 8): 20 min IR light on each area Two days later (day 10): 20 min RED light on each area Week 3, first day (day 15): 20 min IR light on each area Two days later (day 17): 20 min RED light on each area Week 4, first day (day 22): 20 min IR light on each area Two days later (day 24): 20 min RED light on each area
Maintenance regime	Once a week for 15-20 minutes	Once a week for 15-20 minutes	/
Target Population	Individuals with periorbita wrinkles	Individuals with periorbital wrinkles	Individuals with periorbital lines and wrinkles
Anatomical Sites	Periorbital Area	Periorbital Area	Periorbital Area
Location for use	OTC	OTC	OTC
Standard meet	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2

	IEC60601-1-11 IEC62471	IEC60601-1-11 IEC62471	IEC62471
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements

The Conclusions:

Taking into consideration the table for substantial equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the proposed device raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device.