February 24, 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: K214100
Trade/Device Name: Luminice
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 22, 2021
Received: December 29, 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,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K214100

Device Name
Luminice

Indications for Use *(Describe)*
Luminice is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.

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:	K214100
Date prepared:	February 12, 2022
Owner:	Premier North America Inc. 3301 SW 42ND ST., FORT LAUDERDALE, FL 33312-6828, USA Tel: 404-4928133-11
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:	Luminice
Model:	LUMI536
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Device Classification Name:	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Number:	21 CFR 882.5890
Product Code:	NFO
Device Class:	II
Review Panel:	Neurology
Device Description:	Luminice is intended for body skin stimulation and is indicated for over-the-counter cosmetic use. Four (4) stainless steel electrodes, fixed on the Luminice device main body, deliver low level electrical impulses (microcurrent) to targeted locations on the body. The Luminice should be used with 510(k) clearance electroconductive media gel, and it's compatible with NuFACE Gel Primer cleared under K161654.
Indications for use:	Luminice is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.

3. Substantial Equivalence to Predicate device:

The proposed Luminice device has the same, or similar, technological characteristics as the NuBODY Skin Toning Device predicate device. The differences between our proposed device and the cleared predicate device listed below do not raise any safety and effectiveness issues.

Table 1- General Comparison Table

Device Descriptions	**Luminice (New Device)**	**NuBODY Skin Toning Device (Predicate)**	**Remark**
510(k) Number	K214100	K171588	--
Regulation number	21CFR 882.5890	21CFR 882.5890	--
Regulation Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Same
Regulatory Class	Class II	Class II	Same
Classification Name	Stimulator, Transcutaneous	Stimulator, Transcutaneous	Same

	Electrical, Aesthetic Purposes	Electrical, Aesthetic Purposes	
Product Code	NFO	NFO	Same
Regulation Medical Specialty	Neurology	Neurology	Same
Intended use	Luminice is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.	NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.	Same
Indications for use	Over-the-Counter cosmetic use	Over-the-Counter cosmetic use	Same
Anatomic Sites	Areas of the body other than the face	Areas of the body other than the face	Same
Technological Characteristics	The Luminice is a body skin toning device. Its outer case is injection molded ABS resin. The output contacts consist of stainless steel. The Luminice is powered by a rechargeable lithium ion battery. Luminice produces microcurrent that is discharged through four fixed electrodes. To turn the Luminice on, the on/off button is pressed. Ascending tonal beeps and vibration indicate the Luminice device is on. One to three LED lights illuminate indicating the output intensity level and the unit is ready for use. The four electrodes gently glide over the skin to deliver low-level electrical impulses to targeted locations on the body. The Luminice device electrodes are designed for optimal contact with body skin. The Luminice device delivers microcurrent as a constant monophasic square wave comprised of a burst of (10) positive pulses followed by a burst of (10) negative pulses. The microcurrent output continuously alternates between the positive and negative spherical electrodes, and allows the user to adjust the output for a personalized comfort level. The Luminice device	The NuBODY Skin Toning Device is a body skin toning device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spherical electrodes. The NuBODY device is powered by a rechargeable lithium ion battery. NuBODY device produces microcurrent that is discharged through four fixed, smooth spherical electrodes. To turn the NuBODY device on, the on/off button is pressed. Ascending tonal beeps indicate the NuBODY device is on. One to three LED lights illuminate indicating the output intensity level and the unit is ready for use. The four spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the body. The NuBODY device spheres are designed for optimal contact with body skin. The NuBODY device delivers microcurrent as a constant monophasic square wave comprised of a burst of (10) positive pulses followed by a burst of (10) negative pulses. The microcurrent output continuously alternates between the positive and negative spherical	Difference Note 1

	requires the use of a conductive gel. To promote proper use and provide feedback to the user, when the device is is contact with the skin the Luminice device will vibrates and turn on red light.	electrodes, and allows the user to adjust the output for a personalized comfort level. The NuBODY device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuBODY device beeps to cue the user to relocate the NuBODY device approximately every 5 seconds.	

Table 2- Basic Unit Characteristic Comparison

Basic Unit Characteristic		**Luminice (New Device)**	**NuBODY Skin Toning Device (Predicate)**	**Remark**
510(k) Number		K214100	K171588	--
Device Name, Model		Luminice (LUMI536)	NuBODY Skin Toning Device	--
Owner		Premier North America Inc	Carol Cole Company (dba NuFACE)	--
Power Source(s)		Internal rechargeable Lithium ion battery	Internal rechargeable Lithium ion battery	Same
- Method of Line Current Isolation		Type BF	Type BF	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)		-- N/A - Battery operated N/A - Battery operated	-- N/A - Battery operated N/A - Battery operated	Same Same Same
Number of Output channels:		1	1	Same
- Synchronous or Alternating?		N/A - 1 Output channel	N/A - 1 Output channel	Same
- Method of Channel Isolation		N/A - 1 Output channel	N/A - 1 Output channel	Same
Regulated Current or Regulated Voltage?		Both	Both	Same
Software/Firmware/Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip?		Not required due to circuit design	Not required due to circuit design	Same
Automatic No-Load Trip?		Yes	Yes	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/Current Level?	Yes	Yes	Same
Timer Range (minutes)		Yes (1min)	Yes (5min)	Difference Note 2

Compliance with Voluntary Standards?	Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11, ISO 14971	Yes. IEC 60601-1, IEC 60601-1-2 IEC 60529, IEC 60601-2-10 ISO 14971, IEC 60601-1-6 IEC 62366	Difference Note 3
Compliance with 21 CFR 898?	Yes	Yes	Same
Weight (grams)	Approximately 16.5 oz. without power adapter	Approximately 10-14 oz. without power adapter	Difference Note 2
Dimensions (mm) [W x H x D]	Approximately 3.5" x 6.9" x 5.9"	Approximately 2.75" x 6.5" x 6.0"	
Housing Materials & Construction	ABS and stainless steel	Thermoplastic	

Table 3- Output Specification Comparison Table

Output Specifications	**Luminice (New Device)**	**NuBODY Skin Toning Device (Predicate)**	**Remark**
510(k) Number	K214100	K171588	--
Waveform	Monophasic waveform that is delivered in a burst of pulses	Monophasic waveform that is delivered in a burst of pulses	Same
Shape	Voltage Modulated Square	Voltage Modulated Square	Same
Maximum Output Voltage (volts)	28VDC±10% @ open circle 410mV±10% @ 500Ω 1.7V±10% @ 2KΩ 8.1V±10% @ 10KΩ	28 VDC	Same
Maximum Output Current (specify units)	820μA @500Ω	900μA @ 500Ω	Difference Note 4
Output Current when not stimulating	<1μA	<1μA	Same
Pulse width (μsec)	60ms	60ms	Same
Max. pulse frequency (Hz) [or Rate (pps)]	8.3 Hz±10%	8.3 Hz±10%	Same
For interferential modes, only			
a. Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency	Same
For multiphasic waveforms, only			
a. Symmetrical phases	Not Multiphasic	Not Multiphasic	Same
b. Phase Duration (include units)	Not Multiphasic	Not Multiphasic	Same
c. (state range, if applicable)	Not Multiphasic	Not Multiphasic	Same
d. (both phases, if asymmetrical)	Not Multiphasic	Not Multiphasic	Same
Net Charge (μC per pulse)	49.2μC	54μC	Difference Note 4
Maximum Phase Charge (mC/Burst)	0.984	1.08	

Maximum Current Density, (mA/cm², r.m.s.)		0.19mA/cm²	0.468mA/cm²	
Maximum Average Power Density, (mW/cm²)		0.08mW/cm²	4.18mW/cm²	
Burst Mode	(a) Pulses per burst	20	20	Same
	(b) Bursts per second	8.3	8.3	Same
	(c) Burst duration	2.4 s	2.4s	Same
	(d) Duty Cycle: Line (b) x Line	19.92s	20.2s	Similar
ON Time		60ms	60ms	Same
OFF Time		60ms	60ms	Same

Differences between New device and Predicate Device:

Note 1:

The proposed device and predicate device have many similarities in technological characteristics except for electrodes, materials and prompt functions. Both of them have passed the biocompatibility tests. For more stability and better contact, the proposed device uses fixed, oval electrodes without sharp horns, and provides more prompt functions than the predicate device (vibration and red contact light prompt). The proposed device has passed the IEC 60601-1, 60601-1-2 tests. Therefore, these differences will not raise any issues of safety or effectiveness.

Note 2:

The automatic shutdown time limit is slightly different between the proposed device (1min) and the predicate device (5min). Because this design doesn't affect the main functions of device, and the proposed device has passed ES 60601-1, IEC 60601-1-2, IEC 60601-1-11 tests. Therefore, this difference will not raise any issues of safety or effectiveness.

The proposed device is different from the predicate device in housing material, weight, dimensions and appearance. Both of them have passed the biocompatibility tests, IEC 60601-1, 60601-1-2 tests. Therefore, these differences will not raise any issues of safety or effectiveness.

Note 3:

The tests performed by our proposed device are slightly different from those of the predicate device. IEC 60529 is the standard for device waterproof level testing, and the waterproof level of our device has been evaluated in the AAMI/ANSI ES 60601-1 test. The predicate device performed usability test according to IEC 60601-1-6 and IEC 62366 standards. The proposed device referred the user manual of the predicate device K171588, and we attached the Labeling of the predicate device K171588 in our submission. Therefore, these differences will not raise any new issues of safety or effectiveness.

Note 4:

The maximum output current, net charge, maximum phase charge of the proposed device are similar to those of the predicate device. And the maximum current density, maximum average power density of the proposed device are lower than those of the predicate device due to they are calculated by different electrode areas. Both of them meet IEC 60601-2-10 tests. Therefore, these differences don't raise any new safety and effectiveness issues.

4. Non-clinical Testing:

The conclusions drawn from the non-clinical testing below demonstrate that the Luminice is substantially equivalent to the predicate devices K171588. The Luminice 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 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 60601-2-10 Edition 2.1 2016-04: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- IEC 62133 Edition 2.0 2012-12 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 [Including: Corrigendum 1 (2013)];

Biocompatibility testing:

- 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)

Software Validation Testing:

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

5. Conclusions

Based upon comparison to the predicate devices, the Luminice has the same intended uses, with similar technological characteristics as predicate devices. The subject device Luminice is substantial Equivalent to the predicate device K171588.