August 28, 2019

Xtreem Pulse, LLC
% Rhonda Alexander, Ph.D.
Sr. Consultant, Regulatory Strategy
IUVO Consulting, LLC
PO Box 56436
Virginia Beach, Virginia 23456

Re: K190269
Trade/Device Name: PureLift
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 26, 2019
Received: August 27, 2019

Dear Dr. Alexander:

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,

Vivek Pinto, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190269

Device Name
PureLift

Indications for Use *(Describe)*
PureLift is intended for facial stimulation and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

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Date Prepared: 27 August 2019

II. DEVICE

Name of Device: PureLift
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulatory Class: Class II
Product Code: NFO
Regulation Number: 21 CFR 882.5890

III. PREDICATE DEVICE

NuFace Nodel NU-4003
Manufacturer: Carol Cole Company
K Number: K072260

Reference Device: Rejuvenique Model RJV10
K Number: K011935
Manufacturer: Salton, Inc.

IV. DEVICE DESCRIPTION

The PureLift is a hand-held device intended to apply electrical impulses to strategic locations on the face. The PureLift probes are designed for optimal contact with the face. The device continually alternates between the positive and negative probes and allows the user to adjust the settings for personalized comfort level by pressing the up/down button. The intensity starts at (1) and continues to (10).

The device measures 13.4" L x 4.8" W x 4.3" D. Its outer case is injection molded of thermoplastic resin and the probes consist of chrome-plated spheres. The device, powered by a 3.7-volt battery, produces low-level current that is transmitted through the two fixed, smooth spherical probes. To turn the device

on, the power button is pushed. Then LCD screen will be displayed, indicating the unit is ready for use. Users then follow the instructions for use. The two probes gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face.

PureLift is intended to be used with a legally marketed electroconductive media.

The PureLift unit contains a power supply and rechargeable battery. The enclosure is made of medical grade biocompatible plastics and the output contacts (Probes) consist of chrome-plated spheres.

V. INDICATIONS FOR USE

PureLift is intended for facial stimulation and indicated for over-the-counter cosmetic use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Elements of Comparison	**PureLift**	**Predicate Device NuFace (K072260)**	**Reference Device Rejuvenique (K011935)**
Device Name, Model	PureLift	NuFace®	Rejuvenique®
Indications for Use	PureLift is intended for facial stimulation and indicated for over-the-counter cosmetic use.	The NuFace® Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	The Rejuvenique System is indicated for cosmetic use.
Technological Characteristics	The PureLift is a handheld device intended for facial stimulation. Its outer case is injection molded of thermoplastic resin and the two probes consist of chrome-plated spheres. The device, powered by a 3.7V battery, produces electrical impulses that is transmitted through the two fixed, smooth spherical probes. To turn the device on, the push the on/off button. An LCD screen will be displayed, indicating the unit is ready for use. Users then follow the instructions for use. The two probes gently glide	NuFace® is a Facial Toning Device intended for facial stimulation. The device measures 7" L x 2.5" W x 1" D. Its outer case is injection molded of thermoplastic resin, ABS UL 94 HB, and the output contacts (probes) consist of chrome-plated spheres. The device, powered by a 9-volt battery, produces microcurrent that is Discharged through the two fixed, smooth spherical probes. To turn the device on, the thumbwheel is pushed upwards. A Green LED light will Then illuminate, indicating the unit is ready for use.	

Elements of Comparison	PureLift	Predicate Device NuFace (K072260)	Reference Device Rejuvenique (K011935)
	over the skin to deliver low-level electrical impulses to strategic locations on the face.	Users then follow the instructions for use. The two probes gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face.	
Power Source	One 3.7 V Battery	One 9V Battery	Single 9V Battery
Number of output modules	1	1	1
Number of output channels	1 output channel	1 output channel	1 output channel
Regulated current or regulated Voltage?	Regulated current	Both	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes
Automatic Shut off?	Yes	No	Yes
Patient override control?	No	No	
Indicator Display	Yes	Yes	Yes
Timer range	10 minutes only	No Timer	Fixed 16 minutes
Type of protection	Type BF	Type BF	
On/off status	Yes	Yes	Yes
Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	
Biocompatibility	ISO 10993-5, -10	ISO 10993-5, -10	
Waveform	Pulsed Monophasic, alternating polarity	Pulsed Monophasic	pulsed biphasic
Shape	Rectangular Pulses	Rectangular Pulses	Rectangular (+phase, Spike(- phase)
Maximum output voltage	15Vpp (@500Ω) 23Vpp (@2kΩ) 34Vpp(@10kΩ)	158 Mv @ 500Ω 780 Mv @ 2kΩ 2.6 V @ 10kΩ	18.8V @ 500Ω 24.8V @ 2kΩ 28.0V @ 10kΩ
Maximum output current	7mA (@500Ω) 3.2mA(@2kΩ) 0.9mA(@10kΩ)	0.223mA @ 500Ω	37.6mA @ 500Ω 12.4mA @ 2kΩ 2.8mA @ 10kΩ
Output tolerance	+/- 1mA	+/- 10%	+/- 10%
Pulse Width	4μs	112ms	300μs
Frequency (Hz)	1.37kHz～1.73kHz	8.39Hz	8Hz
Symmetrical phases	Not multiphasic	Not Multiphasic	No
Phase duration	4μs	Not determined	300μs (+phase), 124.7ms (-phase, exponential)

Elements of Comparison	PureLift	Predicate Device NuFace (K072260)	Reference Device Rejuvenique (K011935)
Net Charge (μC per pulse train)	0μC per pulse train	0 μC per pulse train	0μC per pulse train
Maximum Phase Charge (μC)	4.52μC @ 500Ω	18.13 μC @ 500Ω	11.3μC @500Ω
Maximum current Density (mA/cm^2)	6.8mA/cm^2 @ 500Ω	0.341mA/cm^2 @ 500Ω	46.4mA/cm^2
Maximum Power Density (μW/cm^2)	23800μW/cm^2 @ 500Ω	3.02μW/cm^2 @ 500Ω	2310.0μW/cm^2
Pulses per burst	30	21	160 pulses
Bursts per second	2740 ～ 3460	9.1	1/240 (per electrode group)
Burst duration	230μs	2.3 seconds	20 seconds
Duty cycle	0.63 ～ 0.80	20.9	1/12
ON Time (seconds)	Constant	Constant	20 seconds/electrode group
OFF Time (Seconds)	None	None	None

VII. PERFORMANCE DATA

Oscilloscope tracings, Vibration, Temperature, Push, Mold Stress, Markings, Mechanical Strength, Drop, Ball, Acoustic, and Accessible Parts tests were also conducted. The device passed or met the requirements of all testing.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject device is considered tissue contacting for a duration of less than 24 hours. The device passed each test, and was found to not be cytotoxic, sensitizing, or irritating.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device. It was found to comply with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

VIII. CONCLUSIONS

The subject device is identical to the predicate in terms of intended use. The technical differences between subject and predicate were addressed using performance data. Thus, it is concluded that the PureLift is substantially equivalent to the predicate device.