October 21, 2022

Xtreem Pulse LLC
Andrew Barile
CEO
353 W. 29 St. Suite 3
New York, New York 10001

Re: K221443
Trade/Device Name: PureLift Pro Plus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 22, 2022
Received: September 23, 2022

Dear Andrew Barile:

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 809); 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,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation 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)*
K221443

Device Name
PureLift Pro Plus

Indications for Use *(Describe)*
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.

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510(k) Summary

XTREEMPULSE

I. SUBMITTER

Applicant:
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UNITED STATES

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Date Prepared: October 20, 2022

II. DEVICE

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

III. PREDICATE DEVICE

Primary Predicate Device: PureLift
Manufacturer: Xtreem Pulse LLC
510(k) Number: K190269

Reference Device: Rejuvenique Model (RJV-10)
Manufacturer: Salton, Inc.
510(k) Number: K011935

IV. DEVICE DESCRIPTION

The PureLift Pro Plus is a hand-held device intended to apply electrical impulses to strategic locations on the face. The PureLift Pro Plus 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 20.7cm (H) x 4.8cm (W) x 4.5cm (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 the green LED light will illuminate 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 with the use of conductive gel.

The PureLift Pro Plus 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

Intended for facial stimulation and indicated for over-the-counter cosmetic use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Elements of Comparison	**Subject Device**	**Predicate Device**	**Reference Device**
	PureLift Pro Plus K221443	**PureLift K190269**	**Rejuvenique K011935**
Indications for Use	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	PureLift is intended for facial stimulation and indicated for over-the-counter cosmetic use.	Rejuvenique System is Indicated for cosmetic use.
Dimensions (HxWxD)	20.7cm x 4.8cm x 4.5cm	13.4in x 4.8in x 4.3in	3in x 4½in x 1¼in
Power Source	One 3.7V Battery	One 3.7V Battery	One 9V Battery
Number of output modes	2	1	1
Number of output channels	1 output channel	1 output channel	1 output channel
Regulated current or regulated voltage?	Regulated current	Regulated current	Regulated Voltage
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes
Automatic Shut off?	Yes	Yes	Yes
Patient override control?	No	No	Yes
Indicator Display	Yes	Yes	Yes
Timer range	10 minutes only	10 minutes only	16 min fixed
Type of protection	Type BF	Type BF	Not publicly available
On/off status	Yes	Yes	Yes
Standards Compliance	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	Not publicly available
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Not publicly available
Waveform	Pulses Monophasic, alternating polarity	Pulses Monophasic, alternating polarity	Pulsed biphasic
Shape	Rectangular Pulses	Rectangular Pulses	Rectangular (+phase) Spike (-phase)
Maximum output voltage	20Vpp(@500Ω) 32Vpp(@2kΩ) 44Vpp(@10kΩ)	15Vpp(@500Ω) 23Vpp(@2kΩ) 34Vpp(@10kΩ)	18.8V @ 500Ω 24.8V @ 2kΩ 28.0V @ 10kΩ
Maximum output current	9mA(@500Ω) 4.4mA(@2kΩ) 1.2mA(@10kΩ)	7mA(@500Ω) 3.2mA(@2kΩ) 0.9mA(@10kΩ)	37.6mA @ 500Ω 12.4mA @ 2kΩ 2.8mA @ 10kΩ
Output tolerance	+/- 1mA	+/- 1mA	+/- 10%
Pulse Width	4µs	4µs	300µs
Frequency (Hz)	1.37kHz～1.73kHz	1.37kHz～1.73kHz	8Hz fixed
Symmetrical phases	Not multiphasic	Not multiphasic	No
Phase duration	4µs	4µs	300µs (+phase) 124.7ms (-phase, exponential)
Net Charge (µC per pulse train)	0µC per pulse train	0µC per pulse train	0µC @500Ω

Elements of Comparison	Subject Device PureLift Pro Plus K221443	Predicate Device PureLift K190269	Reference Device Rejuvenique K011935
Maximum Phase Charge (µC)	5.81µC@500Ω	4.52µC@500Ω	11.3µC @500Ω
Maximum current Density (mA/cm^2)	8.8mA/cm^2@500Ω	6.8mA/cm^2@500Ω	46.4mA/cm^2 @500Ω
Maximum Power Density	39600µW/cm^2	23800µW/cm^2	2.31 mW/cm^2
Pulse per burst	30 pulses	30 pulses	160 pulses
Bursts per second	2740 ~ 3460	2740 ~ 3460	1/240 (per electrode group)
Burst duration	230µs	230µs	20 seconds
Duty cycle	0.63 ~ 0.80	0.63 ~ 0.80	1/12
ON Time (seconds)	Constant	Constant	20 seconds/electrode group

The following technological differences exist between the subject and predicate devices:

- **Dimensions:** As compared to the predicate PureLift device, the PureLift Pro Plus device has a increased height and depth; however, the shape and dimensions of the two fixed, smooth spherical probes located at the distal end of the device remain unchanged. These spheres represent the active part of the device that provides facial stimulation. The device's overall dimensional differences do not alter the manner in which the device is intended to be used nor does it introduce a usability issue. The device's hourglass shape is intended to aid in holding the device as opposed to the predicate PureLift device which was designed with a more oval shape. As such, the dimensional modification does not adversely impact the safety or effectiveness of the device.
- **Maximum output voltage/ current:** The maximum output voltage and maximum output current values for the PureLift Pro Plus device are slightly higher than the predicate PureLift device; however, the energy per second, which is calculated by the output voltage and current for the PureLift Pro Plus device is much lower than the reference device as well as the value specified by the IEC standards. Additionally, the energy for total 10 minutes for the PureLift Pro Plus device is slightly higher than the PureLift predicate device but much lower than the reference device. The difference of the maximum output voltage and maximum output current between the PureLift Pro Plus and both the predicate and reference devices does not adversely impact the safety or effectiveness of the device.
- **Maximum phase charge (µC):** Maximum phase charge is slightly different between the PureLift Pro Plus device and the predicate PureLift device; however, the value is much lower than the reference device indicating substantial equivalence. The difference in value does not increase the risk of skin burn or other injury nor does it raise new questions safety or effectiveness.
- **Maximum current density (mA/cm^2):** The maximum current density of the PureLift Pro Plus device is much lower than the reference device and the difference does not adversely influence safety or effectiveness.
- **Maximum power density (µW/cm^2):** The maximum power density of the PureLift Pro Plus device is slightly larger than the PureLift predicate and reference devices. However, this value is slightly lower than 0.25W/cm^2 which is described as a threshold for reducing the risk of burn in FDA's guidance document for powered muscle stimulators. As such, there is no increased risk of injury or new questions of safety or effectiveness.

VII. PERFORMANCE DATA

Oscilloscope tracings, vibration, temperature, push, mold stress, markings, mechanical strength, drop, ball, acoustic, and accessible parts testing was conducted. The test results confirmed that the device met established design specifications.

Biocompatibility testing

Biocompatibility evaluations for the subject device were conducted in accordance with ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA, and included:

- 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 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 ANSI/AAMI ES60601-1, 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 was conducted and confirmed that the device met established design specifications and conforms to the user needs. The software was assigned a "moderate" level of concern.

VIII. CONCLUSIONS

The subject device is identical to the predicate in terms of intended use. The technological differences between the subject and predicate device were addressed using performance data and confirmed that differences did not raise new questions of safety or effectiveness. Thus, it is concluded that the PureLift Pro Plus is substantially equivalent to the predicate device.