June 21, 2023

Xtreem Pulse
Jacqueline Schmainda
Regulatory Consultant
353 W. 29th St., Suite 3
New York, New York 10001

Re: K230506
Trade/Device Name: PureLift Pro Edition
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: June 20, 2023
Received: June 21, 2023

Dear Jacqueline Schmainda:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K230506

Device Name
PureLift Pro Edition

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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Submitter

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Date Prepared: June 21, 2023

Device

Trade Names: PureLift Pro Edition
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
FDA Panel: Neurology
Regulatory Class: Class II
Product Code: NFO
Regulation Number: 21 CFR 882.5890

Predicate Device

Predicate Type	510(k)	Device Name	Manufacturer
Primary	K221443	PureLift Pro Plus	Xtreem Pulse, LLC
Secondary	K933804	Lectron II Conductive Gel	Cadwell Laboratories, Inc.

Device Description

PureLift Pro Edition

The PureLift Pro Edition device is a hand-held device intended to apply electrical impulses to strategic locations on the face. The device probes are designed for optimal contact with the face. The device continually alternates between the positive and negative probes and allow 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). The outer case is injection molded of thermoplastic resin and the probes consist of chrome-plated spheres. The device is powered by a 3.7-volt battery which produce a 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 Edition 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.

Accessory

PureLift Pro Edition is provided with PureLift Activator Serum, a conductive gel.

Indications for Use

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

Comparison of Technological Characteristics with the Predicate Device

A comparison of the intended use and technological characteristics of the PureLift products to the predicate PureLift device is provided in the following table:

Element of Comparison	PureLift Pro Plus K221443	PureLift Pro Plus Edition K230506 – this submission
Clearance Date	21-Oct-2022	TBD
Indications for Use	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.
Dimensions (HxWxD)	20.7cm x 4.8cm x 4.5cm	20.7cm x 4.8cm x 4.5cm
Power Source	One 3.7V Battery	One 3.7V Battery
Number of output modes	2	1
Number of output channels	1 output channel	1 output channel
Regulated current or regulated voltage?	Regulated current	Regulated current
Software/ Firmware/ Microprocessor Control?	Yes	Yes
Automatic Shut off?	Yes	Yes

Element of Comparison	PureLift Pro Plus K221443	PureLift Pro Plus Edition K230506 – this submission
Patient override control?	No	No
Indicator Display	Yes	Yes
Timer range	10 minutes only	10 minutes only
Type of protection	Type BF	Type BF
On/off status	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
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10
Waveform	Pulses Monophasic, alternating polarity	Pulses Monophasic, alternating polarity
Shape	Rectangular Pulses	Rectangular Pulses
Maximum output voltage	20Vpp(@500Ω) 32Vpp(@2kΩ) 44Vpp(@10kΩ)	16.6Vpp(@500Ω) 27.0Vpp(@2kΩ) 38.4Vpp(@10kΩ)
Maximum output current	9mA(@500Ω) 4.4mA(@2kΩ) 1.2mA(@10kΩ)	7.7mA(@500Ω) 3.6mA(@2kΩ) 1.0mA(@10kΩ)
Output tolerance	+/- 1mA	+/- 1mA
Pulse Width	4µs	4µs
Frequency (Hz)	1.37kHz～1.73kHz	1.37kHz～1.73kHz
Symmetrical phases	Not multiphasic	Not multiphasic
Phase duration	4µs	4µs
Net Charge (µC per pulse train)	0µC per pulse train	0µC per pulse train
Maximum Phase Charge (µC)	5.81µC@500Ω	4.97µC@500Ω
Maximum current Density (mA/cm2)	8.8mA/cm2@500Ω	7.5mA/cm2@500Ω
Maximum Power Density	39600µW/cm2	29250µW/cm2
Pulse per burst	30 pulses	30 pulses
Bursts per second	2740 ～ 3460	2740 ～ 3460
Burst duration	230µs	230µs
Duty cycle	0.63 ～ 0.80	0.63 ～ 0.80
ON Time (seconds)	Constant	Constant

A comparison of the PureLift Activator Serum accessory to the predicate conductive gel is provided in the following table:

Element of Comparison	PureLift Activator Serum (accessory) K230506 – this submission	Lectron II Conductive Gel K933804
Intended Use	NA – the PureLift Activator Serum is only intended for use with PureLift devices in accordance with the intended use for these devices.	NA – a 510(k) summary is not publicly available.
Ingredients	Water, glycerin, chondus crispus extract (seaweed), phenoxyethanol, sodium hyaluronate, propylene glycol, chrophenesin, ethylhexyglycerin, disodium EDTA, sodium dehyroacetate, palmityl tripeptide-5, citric acid	NA – a 510(k) summary is not publicly available.
Performance Testing	Comparisons to the Predicate Gel: • Conductivity • Maximum Voltage • Maximum Current • Frequency • Pulse Width	Unknown
Biocompatibility	ISO 10993-5 ISO 10993-10	NA – a 510(k) summary is not publicly available.

Performance Data

No new or repeat design verification or design validation was required to support the substantial equivalence of the PureLift Pro Edition stimulator.

An analysis of the conductivity testing of the PureLift Activator Serum was performed. The analysis demonstrated that the PureLift Activator Serum has similar conductivity as the Lectron II conductive gel.

Biocompatibility

No new or repeat biocompatibility testing was required to support the substantial equivalence of the PureLift Pro Edition stimulator.

The following biocompatibility evaluations of the PureLift Activator Serum were conducted:

- ISO 10993-5, Cytotoxicity
- ISO 10993-10, Sensitization
- ISO 10993-10, Irritation

Biocompatibility evaluations confirmed that the PureLift Activator Serum is non-cytotoxic, non-sensitizing, and non-irritating.

Electrical safety and electromagnetic compatibility (EMC)

No new or repeat EMC or electrical safety testing was required to support the substantial equivalence of the PureLift Pro Edition.

Software verification and validation

No new or repeat software verification or validation testing was required to support the substantial equivalence of the PureLift Pro Edition.

Conclusions

The subject PureLift Pro Edition device is identical to the predicate device in terms of intended use and primary technological characteristics. Any differences between these devices were reviewed and confirmed to raise no new questions of safety or effectiveness. Additionally, the PureLift Activator Serum was assessed using performance data which confirmed that any differences between it and the predicate conductive gel did not raise new questions of safety or effectiveness. Thus, it is concluded that the PureLift Pro Edition is substantially equivalent to the predicate device.