



March 6, 2025

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

Re: K243587

Trade/Device Name: PureLift GLOW

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief

Regulatory Class: Class II

Product Code: NFO, OHS

Dated: February 4, 2025

Received: February 4, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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  
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Enclosure

## Indications for Use

Submission Number (if known)

K243587

Device Name

PureLift GLOW

Indications for Use (Describe)

PureLift GLOW is intended for facial and neck stimulation, treatment of wrinkles, treatment of mild to moderate inflammatory acne, 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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## Contact Details

21 CFR 807.92(a)(1)

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## Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PureLift GLOW
Common Name	Transcutaneous electrical nerve stimulator for pain relief
Classification Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Number	882.5890
Product Code(s)	NFO

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221443	PureLift Pro Plus	NFO
K223482	reVive Light Therapy® Wrinkle and Acne LED Device	OHS
K201782	NuFace Trinity Plus Device	NFO

## Device Description Summary

21 CFR 807.92(a)(4)

PureLift GLOW is a hand-held device intended to apply electrical impulses to strategic locations on the face and neck and Light Emitting Diode (LED) technology that is intended for the treatment of wrinkles and mild to moderate inflammatory acne.

The PureLift GLOW probes are designed for optimal contact with the face while the LED technology is not intended to come into contact with the user. 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 LED treatment area is approximately 36.3cm<sup>2</sup> and available five levels of blue (465nm) and red (634nm) wavelengths.

The device housing is injection molded of biocompatible thermoplastic resin and the probes consist of chrome-plated spheres. The device, powered by a 3.7-volt rechargeable battery, produces low-level current that is transmitted through the two fixed, smooth spherical probes. To turn the device on, the power button is pressed, and a green light illuminates to indicate that 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 and neck with the use of a conductive gel and the LED light is directed to the treatment area.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

PureLift GLOW is intended for facial and neck stimulation, treatment of wrinkles, treatment of mild to moderate inflammatory acne, and indicated for over-the-counter cosmetic use.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device is intended for facial and neck stimulation, treatment of wrinkles, treatment of mild to moderate inflammatory acne, and indicated for over-the-counter cosmetic use. The device has the same indication for use in comparison to the following predicate/reference devices:

- K223482 Predicate Device: intended for the treatment of wrinkles and mild to moderate inflammatory acne
- K210782 Reference Device: intended for facial and neck stimulation and over-the-counter cosmetic use

## Technological Comparison

21 CFR 807.92(a)(6)

The subject has similar technological characteristics as comparison to the predicate/reference device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following bench performance testing has been performed for the PureLift GLOW device:

- Power input
- Limitation of voltage, current or energy
- Accuracy of controls and instructions and protection against hazardous outputs
- Leakage currents and patient auxiliary currents
- Dielectric strength
- Accessible parts
- Acoustic energy
- Ball pressure
- Drop test
- Environment
- Marking
- Mold stress relief
- Push test
- Temperature
- Vibration

Clinical testing was not required to support a substantial equivalence determination.

### Substantial Comparison Table

Item	PureLift GLOW	PureLift Pro Plus	NuFace Trinity Plus	reVive Light Therapy Wrinkle and Acne LED
510(k) Number	K243587	K221443	K201782	K223482
Regulation	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 878.4810
Product Code(s)	NFO/OLP	NFO	NFO	OHS/OLP
Class	Class II	Class II	Class II	Class II
Use Type	Over-the-Counter (OTC)	Over-the-Counter (OTC)	Over-the-Counter (OTC)	Over-the-Counter (OTC)
Device Name	Intended for facial and neck stimulation, treatment of wrinkles, treatment of mild to moderate inflammatory acne, and indicated for over-the-counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	The NuFace Trinity Plus Device is intended for facial and neck stimulation and indicated for over-the-counter cosmetic use.	The reVive Light Wrinkle and LED Device is intended for treatment of wrinkles and mild to moderate inflammatory acne.
Irradiance Source	LED	N/A	N/A	LED
Anatomic Site	Face and Neck	Face	Face and Neck	Face
Treatment Area	36.3cm <sup>2</sup>	N/A	N/A	7 cm <sup>2</sup>
Type of Energy Output	Microcurrent	Microcurrent	Microcurrent	N/A
Treatment Method	Place directly on the skin	Place directly on the skin	N/A	Place directly on the skin
Treatment Time	10 minutes	10 minutes only	N/A	3 minutes
Materials	Thermoplastic resin enclosures, chrome-plated spheres	Thermoplastic resin enclosures, chrome-plated spheres	N/A	N/A
Wavelengths (Wrinkle Treatment)	634nm	N/A	N/A	605nm, 630nm, 660nm, 880nm
Wavelengths (Acne Treatment)	465nm	N/A	N/A	415nm, 630nm

<b>Item</b>	<b>PureLift GLOW</b>	<b>PureLift Pro Plus</b>	<b>NuFace Trinity Plus</b>	<b>reVive Light Therapy Wrinkle and Acne LED</b>
Dimensions (H x W x D)	14.6cm x 6.1cm x 4.4cm	20.7cm x 4.8cm x 4.5cm	5.2in x 2.6in x 1.6in	N/A
Power Source	One 3.7V battery	One 3.7V battery	Internal rechargeable Lithium Ion battery	Battery or universal USB power source
Number of output modes	2	2	N/A	N/A
Number of output channels	1	1	1	N/A
Regulated current or regulated voltage	Regulated current	Regulated current	Both	N/A
Software / Firmware / Microprocessor Control	Yes	Yes	Yes	N/A
Automatic Shut Off	Yes	Yes	Yes	N/A
Patient Override Control	No	No	Yes	N/A
Indicator Display	Yes	Yes	N/A	N/A
Timer Range	10 minutes only	10 minutes only	N/A	N/A
Type of Protection	Type BF	Type BF	Type BF	N/A
On / Off Status	Yes	Yes	Yes	N/A
Standards Compliance	ANSI/AAMI ES60601-1 IEC 60601-1-2	ANSI/ AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	N/A	ANSI/ AAMI ES 60601-1 IEC 60601-1-2
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	N/A	ISO 10993-5 ISO 10993-10

Item	PureLift GLOW	PureLift Pro Plus	NuFace Trinity Plus	reVive Light Therapy Wrinkle and Acne LED
Waveform	Pulses monophasic, alternating polarity	Pulses monophasic, alternating polarity	N/A	N/A
Shape	Rectangular pulses	Rectangular pulses	N/A	N/A
Maximum Output Voltage	9mA (@500Ω) 4.4mA (@2kΩ) 1.2mA (@10kΩ)	9mA (@500Ω) 4.4mA (@2kΩ) 1.2mA (@10kΩ)	N/A	N/A
Maximum Output Current	20Vpp (@500Ω) 32Vpp (@2kΩ) 44Vpp (@10kΩ)	20Vpp (@500Ω) 32Vpp (@2kΩ) 44Vpp (@10kΩ)	N/A	N/A
Output Tolerance	± 1mA	± 1mA	N/A	N/A
Pulse Width	4 μs	4 μs	N/A	N/A
Frequency (Hz)	1.37kHz ~ 1.73kHz	1.37kHz ~ 1.73kHz	N/A	N/A
Symmetrical Phases	Non multiphasic	Non multiphasic	N/A	N/A
Phase Duration	4 μs	4 μs	N/A	N/A
Net Charge (μC per pulse train)	0 μs per pulse train	0 μs per pulse train	N/A	N/A
MaximumPhase Charge (μC)	5.81 μC @500Ω	5.81 μC @500Ω	N/A	N/A
Maximum Current Density (mA/cm <sup>2</sup> )	8.8 mA/cm <sup>2</sup> @500Ω	8.8 mA/cm <sup>2</sup> @500Ω	N/A	N/A
Maximum Density Power	39600 μW/cm <sup>2</sup>	39600 μW/cm <sup>2</sup>	N/A	N/A
Pulse Per Burst	30 pulses	30 pulses	20 (10 positive and 10 negative)	N/A
Burst Per Second	2740 ~ 3400	2740 ~ 3400	8.3 (@ 8.3 Hz)	N/A
Burst Duration	230 μs	230 μs	2.4s (@8.3 Hz)	N/A
Duty Cycle	0.63 ~ 0.80	0.63 ~ 0.80	Duty cyle: 50% time per burst: 20.2s	On N/A
ON Time (seconds)	Constant	Constant	60 ms (@8.3 Hz)	N/A

Item	PureLift GLOW	PureLift Pro Plus	NuFace Trinity Plus	reVive Light Therapy Wrinkle and Acne LED
Indicator Displays	On/off status, low battery, voltage current level	On/off status, low battery, voltage current level	On/off status, low battery, voltage current level	N/A
Accessory to Device	PureLift Activator Serum (biocompatible, 510(k) cleared per K221443) or other cosmetic conductive gel or serum	PureLift Activator Serum (biocompatible, 510(k) cleared per K221443)	NuFACE Gel Primer (biocompatible, 510(k) cleared per K161654)	N/A