August 20, 2024

Foreo Inc.
% Danijela Domljanovic
Consultant
DD Consulting
401-4080 Living Arts Drive
Mississauga, ON L5B 4N3
Canada

Re: K241102
Trade/Device Name: Luna 4 plus
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS, NFO
Dated: April 16, 2024
Received: April 22, 2024

Dear Danijela Domljanovic:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2024.08.20 19:33:18 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241102

Device Name
Luna 4 plus

Indications for Use *(Describe)*
Luna 4 plus is a Near-Infrared Heated Cleansing Device With Red LED/NIR light & Microcurrent Massage.

Microcurrent: indicated for facial stimulation
RED+NIR: indicated to treat periorbital wrinkles

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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K241102 - LUNA 4 plus 510(k) Summary

Date Prepared:	08/20/2024
510(k) Submitter:	FOREO, Inc. 1525 E. Pama Lane Las Vegas, NV 89119
Contact:	Danijela Domljanovic E: regulatoryna@foreo.com P: 647-928-6919

Device Names:

Device Trade/ Proprietary Name:	Luna 4 plus
Common or Usual Name:	Luna 4 plus
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 890.4810 21 CFR 882.5890
Product Code:	OHS, NFO

Predicate Device:

The legally marketed predicate devices to which FOREO, Inc. is claiming equivalence for over-the-counter use:

510(k) Number:	K162652
Manufacturer:	Guangzhou LETA Testing Technology Co., Ltd
Product Code:	OHS, NFO, OLP

510(k) Number:	K201906
Manufacturer:	Carol Cole Company dba NuFACE
Product Code:	NFO

510(k) Number:	K212155
Manufacturer:	Theragun, Inc
Product Code:	OHS, OLP, IRO

Device Description:

Luna 4 plus has multiple functions combined in a single device, like RED+NIR LED Treatment for wrinkle reduction

The device emits visible red/IR light (Red: 630nm +/- 10nm, NIR 830nm +/-10nm.) for elevating tissue temperature in improving appearance of facial wrinkles.

Microcurrent to target facial stimulation

Two microcurrent pins at the back for a targeted toning massage, emitting microcurrent electrical therapy to deliver skin stimulation where maximum power delivered to the load is controlled and limited by integral software.

Luna 4 plus is a single device powered by a rechargeable battery. A controller is integrated on the back to control the device, such as turn on/off the device, mode buttons.

Rechargeable Li-battery contained in the controller with a USB cable accessible to target it. To use the device, the user should use the controller to operate.

Intended Use:

Luna 4 plus is a Near-Infrared Heated Cleansing Device with Red LED/NIR light & Microcurrent Massage

Microcurrent: indicated for facial stimulation
RED+NIR: indicated to treat periorbital wrinkles

Technological Characteristics:

LUNA 4 plus is substantially equivalent to that of its predicates and its technological characteristics remain unchanged.

Non-Clinical Testing:

To establish substantial equivalence to the predicate devices, LUNA 4 Plus was tested to the applicable standards for electrical safety, EMC, and biocompatibility, as listed in the Substantial Equivalence Comparison Table below. Additionally, LUNA 4 Plus underwent lab bench performance testing to characterize its electrical stimulation output, including performance testing of the Anti-Shock System and performance under overload conditions. Usability studies conducted demonstrate that the device is substantially equivalent to the predicate given the new indications.

Performance Standards:

Luna 4 plus is substantially equivalent to that of its predicates and complies to FDA performance standards set forth in 21 CFR §898.

Product Safety and EMC performance testing was conducted for the following aspects:

1. Electrical and Constructional Safety in accordance with IEC 60601-1
2. Electromagnetic Compatibility (EMC) in accordance with IEC 60601-1-2

Thus, with respect to Safety and EMC, Luna 4 plus is substantially equivalent to its predicates.

Table 1: Substantial Equivalence Comparison Table

Features	Subject Device	Predicate	Predicate Device	Predicate Device	Remarks
Regulatory Information					
Device Name	Luna™ 4 plus	EP-300	TheraFace LED	Nuface Trinity ELE Plus Pro	/
510(K) No.	Applying	K162652	K212155	K201906	/
Regulation Number	878.4810 882.5890	882.5890	878.4810	882.5890	Different
Regulation name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Transcutaneous Electrical Nerve Stimulator for Pain Relief	Laser surgical instrument for use in general and plastic surgery and in dermatology	Transcutaneous Electrical Nerve Stimulator for Pain Relief	Different
Regulatory Class	II	II	II	II	Same
Product Code	OHS, NFO	OHS,NFO,OLP	OHS, OLP, IRO	NFO	Similar
Intended Use	1.The Red + IR light is intended to treat periorbital wrinkles 2.The microcurrent is intended to treat facial stimulation	(1) The EMS mode is indicated for facial stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne	The device can work in multiple function modes as following with different indication for use: 1.The red light is intended to treat periorbital wrinkles. 2.The blue light is intended to treat mild to moderate inflammatory acne. 3.The Red + IR is intended to treat periorbital wrinkles.	The Trinity ELE Plus Pro devices are intended for facial stimulation and indicated for over-the-counter cosmetic use.	Similar
Indications for Use	OTC Cosmetic Use	OTC Cosmetic Use	OTC Cosmetic Use	OTC Cosmetic Use	Same

Safety mechanism	Thermal sensor and heat stabilizer: These measure the skin temperature, stabilize the heat energy and prevent overheating. When the skin temperature reaches 42°C - 43°C, the stabilizer will automatically stop emitting heat, until the skin temperature lowers enough for the stabilizer to resume heating. Anti-Shock system: Detect the current through the skin by monitoring voltage on the feedback resistor, and feedback to the microprocessor to ensure the current keeps relatively stable and smooth.	Unknown	The device has an automatic reset thermal limiter that shuts off the device to prevent overheating and fire	Unknown	Different
Device Characteristics					
Apply Parts	Face	Face	Face	Face	Same
Treatment regimen	Yes (1-4 min) (adjustable)	Yes (10 mins)	Red light: 5 - 7 minutes per treatment zone Red+IR: 5 - 7 minutes per treatment zone	Yes (21 mins)	Different
Use Environment	Home Use, lay users	Home Use, lay users	Home Use, lay users	Home Use, lay users	Same
Power Source(s)	Internal rechargeable Lithium battery	Internal rechargeable Lithium battery	Internal rechargeable Lithium battery	Internal rechargeable Lithium battery	Same
Maximum charging time	2 hours	Unknown	1 hour	12 hours	Different Note 1

Indicator for Display	On/off	Yes	Yes	Yes	Yes	Same
	Low-battery	Yes	Yes	Yes	Yes	Same
	Current level	Yes	Yes	Yes	Yes	Same
Regulated Current or Regulated Voltage		Regulated Voltage	Regulated Voltage	Both	Both	Similar
Software/Firmware/ control		Yes	Yes	Yes	Yes	Same
Automatic Overload Trip		Not required due to circuit design	Yes	Yes	Not required due to circuit design	Similar
Automatic Shut Off		Yes	Yes	Yes	Yes	Same
Micro current Function						
Electrodes		1	2	N/A	1	Similar
Method of line current isolation		Type BF	Type BF	N/A	Type BF	Same
Patient leakage current						/
Normal condition		N/A-Battery operated	N/A-Battery operated	N/A	N/A-Battery operated	Same
Single fault condition		N/A-Battery operated	N/A-Battery operated	N/A	N/A-Battery operated	Same
Number of output channels		1	1	N/A	1	Same
Synchronous or alternating		N/A-1 Output channel	N/A-1 Output channel	N/A	N/A-1 Output channel	Same
Method of channel isolation		N/A-1 Output channel	N/A-1 Output channel	N/A	N/A-1 Output channel	Same
Patient override control		Yes	Yes	N/A	Yes	Same
Waveform		Pulsed monophasic, alternating polarity, charge-balanced	Pulsed Biphasic	N/A	Pulsed Biphasic	Different Note 2

Waveform shape	Modulated square	Rectangular	N/A	Modulated square	Different Note 2
Pulse width range	290 µs	4ms	N/A	Varies w/ Frequency (60 msec @ 8.33Hz)	Different Note 2
Maximum RMS Output Voltage	0.28V @500Ω 1.11V @2KΩ 5.50V @10KΩ	1.49V @500Ω 2.48V @2kΩ 10.6V @10kΩ	N/A	208 mV @ 500 Ω 840 mV @ 2 kΩ 4.3 V @ 10 kΩ	Different Note 2
Maximum RMS output Current	560µA @500Ω 555µA @2KΩ 552µA @10KΩ	2.98mA @500Ω 1.24mA @2kΩ 1.06mA @10kΩ	N/A	297 µA @ 500 Ω 299 µA @ 2 kΩ 301 µA @ 10 kΩ	Different Note 2
Maximum RMS Current Density	1.37 mA/cm² @500 Ω	0.524mA/cm² @500 Ω	N/A	1.165 mA/cm² @10K Ω	Different Note 2
Maximum RMS Power Density	0.38 mW/cm² @500 Ω	0.216 mW/cm² @500 Ω	N/A	3.525 mW/cm² @10K Ω	Different Note 2
Frequency Range	46Hz	60Hz	N/A	0.3 – 50 Hz (Default 8.3 Hz)	Different Note 2
Output tolerance	+/- 10% (RMS)	unknown	N/A	+/- 10% (RMS)	Same
Maximum Net Charge	0 µC(charge-balanced)	0 µC	N/A	N/A - Battery Operated	Different Note 2
Maximum RMS phase charge per burst	0.16µC@ 500Ω	Unknown	N/A	18.17 µC @ 10K Ω	Different Note 2
Maximum RMS charge density	0.39µC/cm2	Unknown	N/A	Unknown	Different Note 2
Output RMS current when not simulating	<1 µA	Unknown	N/A	Unknown	Different Note 2
For interferential modes, only					/
a. Beat Frequency (Hz)	No Beat Frequency	Unknown	N/A	No Beat Frequency	Same
For multiphasic waveforms, only					/
Symmetrical phases	Not Multiphasic	Unknown	N/A	Not Multiphasic	Same

b. Phase Duration (include units) c. (state range, if applicable) d. (both phases, if asymmetrical)	No Beat Frequency	Unknown	N/A	No Beat Frequency	Same
Burst mode information					/
a. Pulses per burst	2	Unknown	N/A	20	Different Note 2
b. Pulses per second	100	Unknown	N/A	varies w/ Frequency (8.3 @8.33Hz)	Different Note 2
c. Burst duration (sec)	0.02	Unknown	N/A	Varies w/ Frequency (2.4 @ 8.33Hz)	Different Note 2
d. Duty Cycle (%)	NA	Unknown	N/A	50	Different Note 2
On time(sec)	372 µs	Constant	N/A	Varies w/ Frequency (60ms @ 8.33Hz @ 50% Duty Cycle)	Different Note 2
Off time(sec)	10.12 ms	None	N/A	Varies w/ Frequency (60ms @ 8.33Hz @ 50% Duty Cycle)	Different Note 2
For LED Red and NIR Light Irradiation function					
Visible LED Wavelength	RED light: 633nm±10nm Red+IR: 633±10nm / 850nm±10nm	Red-light: 630±10nm Blue light: 415±10nm	Red light: 633nm±10nm Red+IR: 633±10nm /830nm±10nm	N/A	Different Note 3
Optical Power Density	RED+IR:63 mW/cm²	Red light: 80 mW/cm2 Blue light: 50mW/cm2	Red light: 73±5 mW/cm² Red+IR: 73±5/55±5 mW/cm²	N/A	Different Note 3
Additional Features					
Weight	150g	125g	230g	180g	Different Note 4

Dimensions (mm)	82*38*102 mm	140.5 x 61 x 76 mm	140*65*55 mm	127*76*25mm	Different Note 4
Housing material and construction	Body-safe silicone, ABS plastic, copper, glass, gold, zinc alloy	Console: ABS plastic	PC Plastic & Stainless Steel	ABS Thermoplastic, Chromium	Similar
User interface	Power button on/Off Deep cleansing mode button Regular cleansing mode button	Power button on/Off Switch button Shift Adjust Intensity LCD Screen Photon Light	Power Button Percussive Therapy Button Ring button RED+IR LED Ring	multi-function button on/off BOOST button Release Button Power down/up button	Similar
Environment for operating	Temperature: 5 ~ 40° C Relative humidity:40% ~ 80%	Temperature: 5~ 40° C Relative humidity: <93% RH	Temperature: 0 ~ 40° C Relative humidity: <93% RH	Temperature: 10 ~ 40° C Relative humidity:30~ 75%rH	Similar
Environment for storage	Temperature: -10 ~ 50° C Relative humidity: 30%~ 80%	Temperature: -25° C ~ 50° C Relative humidity: 10~95% RH	Temperature: -25 ~ 50° C Relative humidity: 10~95%	Temperature: -10 ~ 55° C Relative humidity: 10~90%	Similar
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Similar
Electrical Safety	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-2-10	IEC 60601-1, IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1	Similar
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Compliance with 21 CFR 898	Yes	Yes	Yes	Yes	Same

Comparison in details

Note 1:
The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has been tested under standard IEC 62133-2, so this difference should not raise any safety/effectiveness questions.

Note 2:
Though the electrical microcurrent stimulation characteristics of the LUNA 4 Plus (including effective area, pulse width range, burst characteristics, and total output power density) differ slightly from the predicate devices, these differences are intended to provide improved user experience and do not significantly affect the subject device's safety and effectiveness relative to the predicates. In particular, the LUNA 4 Plus' output power density is lower than the secondary predicate (K201906), and adequate electrical safety and performance testing were conducted according to applicable standards for nerve and muscle stimulators (including IEC 60601-1 and IEC 60601-2-10) as well as lab bench performance evaluation.

Note 3:
Although differences exist for LED wavelength and Optical Power Density, additional usability report and bench evaluation are performed to ensure its safety and effectiveness.

Note 4:
Although the appearance, dimensions, and environment storage are different between the subject and predicate device, these differences have no impact and do not raise any safety/effectiveness problems.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR part 807 and based on the relative information provided in this premarket notification, we conclude the LUNA 4 plus is substantially equivalent to the EP-300, TheraFace LED and Nuface Trinity ELE Plus Pro with regards to safety and effectiveness.