July 17, 2023

Neauvia North America
Joy Willard
Director of Quality, Regulatory, and Clinical Affairs
8480 Honeycutt Road
Raleigh, North Carolina 27615

Re: K230077
Trade/Device Name: LaserME
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: GEX,
Dated: June 15, 2023
Received: June 16, 2023

Dear Joy Willard:

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,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K230077

Device Name
LaserME

Indications for Use *(Describe)*

The LaserMe is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The LaserMe is further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

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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This 510(K) Summary of safety and effectiveness for the LaserME is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant:	Neauvia North America
Address:	Neauvia North America 8480 Honeycutt Road Raleigh, NC 27615
Contact Person:	Joy Willard
Contact Information:	984-777-5296 joy@neauvia-us.com
Preparation Date:	January 23, 2022
Device Trade Name:	LaserME
Common Name:	Powered laser surgical instrument
Regulation Name:	21 CFR 878.4810, Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Product Codes:	GEX
Legally Marketed Predicate Device:	Emerge Fractional Laser K111840
Regulatory Class:	Class II Prescription Use
Description of the LaserME Laser System:	**LaserME** is a non-ablative diode laser. The device is equipped with a diode laser with a wavelength of 1470 nm and a maximum power of 2W, intended for non-ablative skin resurfacing. The device works by punctuating the skin (epidermis) with several micro laser beams. The points are evenly spaced with adjustable spacing from 1mm to 4mm. The energy delivered to a single point is regulated from 5mJ to 50mJ.

Intended use of LaserME	The LaserMe is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The LaserMe is further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

Comparison to the Predicate Device:

Specifications	LaserME	Emerge Fractional Laser K111840
Laser type	Diode	Diode
Power Supply	112-240 VAC, 50/60Hz	110-240 VAC, 50/60Hz
Output wavelength	1470 +/- 20nm	1410nm
Pulse Time	30ms	Max 20ms
Applicator Window	12 x 12mm	12mm x 8mm
Energy	5mJ-50mJ	10mJ to 30mJ
No. of microbeams	Up to 70	Up to 70
Repetition Frequency	Up to 18Hz	Up to 30Hz
Weight	4 Kg	Handpiece: 250 g Base: 3 kg
Dimensions	156 x 335 x 421 mm	Unknown
Indications for use	The LaserMe is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The LaserMe is further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.	The Emerge Fractional Laser is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The Emerge Fractional Laser is further indicated for treatment of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

Non-clinical Testing:	The following performance data was provided in support of the substantial equivalence determination: IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.

	IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility IEC 60601-2-22 Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process Histological assessment in ex vivo tissue to demonstrate that the extent of the damage induced due to the worst-case pulse energy of the subject device is comparable to the damage induced due to the worst-case pulse energy of the predicate device.
Clinical Testing:	The thermal effects of the LaserME and tissue healing process were evaluated in 18 healthy volunteers. The study was conducted by exposing human subjects to a single laser treatment followed by histology analysis performed immediately, 3 and 10 days post treatment. The study results show that the LaserMe behaved as intended.

Conclusion: Based on the comparison and analysis above, the proposed subject device LaserME is determined to be Substantially Equivalent (SE) to the predicate device.