June 2, 2022

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

Re: K213261
Trade/Device Name: EpilME
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: May 4, 2022
Received: May 5, 2022

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,

Purva Pandya
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)*
K213261

Device Name
EpilME

Indications for Use *(Describe)*

Laser EpilME with EpilME applictor is indicated for use in surgical and aesthetic applications in the medical specialties of general and plastic surgery, and dermatology.

The EpilME is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The EpilMe with EpilME Applicator is intended for:
- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Hair removal, permanent hair reduction*
- Treatment of benign pigmented lesions

*Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K Summary
EpilME Laser K213261

This 510(K) Summary of safety and effectiveness for the EpilME is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

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:	June 2, 2022
Device Trade Name:	EpilME Laser
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:	LightSheer Desire Laser System K170179
Regulatory Class:	Class II Prescription Use
Description of the EpilME Laser:	The Laser EpilME with EpilME applicator is an electro-optical device consisting of a laser console and applicator. The laser console provides a graphical user interface and software for control of the system, the needed electronics to control and power the accessories, handpiece connection port and cooling system.

Intended use of EpilME Laser:	Laser EpilME with EpilME Applicator is indicated for use in surgical and aesthetic applications in the medical specialties of general and plastic surgery, and dermatology. The EpilME is intended for use on all skintypes (Fitzpatrick skin types I – VI), including tanned skin. The EpilMe with EpilME Applicator is intended for: • Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascularlesions and leg veins • Treatment of pseudofolliculitis barbae (PFB) • Hair removal, permanent hair reduction* • Treatment of benign pigmented lesions *Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measuredat 6, 9, and 12 months after the completion of a treatment regime.
Performance Data:	IEC 60601-1:2005, AMD1:2012 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance. IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility IEC 60601-2-22: 2007 Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

	EpilMe Laser K213261	**LightSheer Desire K170179**	
Indication for Use Comparison			
Indication for Use	Laser EpilME with EpilME Applicator is indicated for use in surgical and aesthetic applications in the medical specialties of general and plastic surgery, and dermatology. The EpilME is intended for use on all skintypes (Fitzpatrick skin types I – VI), including tanned skin. The EpilMe with EpilME Applicator is intended for: • Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascularlesions and leg veins • Treatment of pseudofolliculitis barbae (PFB) • Hair removal, permanent hair reduction* • Treatment of benign pigmented lesions *Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measuredat 6, 9, and 12 months after the completion of a treatment regime.	The LightSheer Desire System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire System is intended for use on all skintypes (Fitzpatrick skin types I – VI), including tanned skin. The LightSheer Desire System with LightSheer ET/XC 805nm Laser Handpieces are intended for: • Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins • Treatment of pseudofolliculitis barbae (PFB) • Hair removal, permanent hair reduction* • Treatment of benign pigmented lesions *Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Same

Technical Comparison		
	EpilME	**LightSheer Desire K170179**
Power supply	220 - 240 VAC, 50/60Hz, max 2600 VA	100-240 VAC, 15 A max. 50/60 Hz
Output wavelength	808 nm +/- 20nm	790-830nm (805 nm nominal)
Pulse Duration	50 ms	5-400ms
Spot Size	10mm x 21 mm	9mm x 9mm 12mm x 12mm
Max Energy	Up to 80J	Up to 81J
Rep Rate	up 12 Hz	3 Hz

Conclusion: The EpilMe's intended use, indications for use and technical specifications are substantially equivalent to the predicate device. There are no new questions of safety raised.

`