February 10, 2023

TermoSalud
℅ Connie Hoy
Regulatory Consultant
Hoy and Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K223680
Trade/Device Name: Eneka Pro
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: December 8, 2022
Received: December 8, 2022

Dear Connie Hoy:

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)*
K223680

Device Name
Eneka Pro

Indications for Use *(Describe)*
Indications for use for Eneka Pro diode laser hair removal system with 808nm applicators include:

• Hair Removal with Dynamic (DHR) and Fast Dynamic (FDHR) mode intended for permanent reduction in hair regrowth, defined as a 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.

• Treatment of Pseudofolliculitis barbae (PFB).

• Use on all skin types (Fitzpatrick I-VI)

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."

K223680

510(K) Summary
Eneka Pro

This 510(K) Summary of safety and effectiveness for the Eneka Pro 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	TermoSalud
Address	Ataulfo Friera Tarfe, 8 -33211 Gijón, Spain
Contact Person	Connie Hoy, Regulatory Consultant
Contact Information	conniehoy@hoyregulatory.com (530) 908-4903
Preparation Date	December 8, 2022
Device Trade Name	Eneka Pro
Common Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810
Product Code	GEX
Regulatory Class	II
Legally Marketed Predicate Device	Primelase (K191321)

Device Description:
The Eneka Pro is a non-invasive diode laser based system used for Hair Removal. The system is based on a single wavelength diode laser with 2 handpieces (spot sizes 20x9mm and 34x14mm) and the ability to control the pulse width, frequency and power. The Hair Removal Laser is intended for use on all skin types (Fitzpatrick skin types I-VI).

Indications for use:
Indications for use for Eneka Pro diode laser hair removal system with 808nm applicators include:

- Hair Removal with Dynamic (DHR) and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a 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.
- Treatment of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI)

Substantial Equivalence—Technological Characteristics:

Specification	Subject Device	Predicate Device	Comparison
Principle of operation	AlGaAs Laser diode array	AlGaAs Laser diode array	Same
Laser Wavelength	808nm	755 nm, 810 nm, 810 – 1060 nm	Same. This submission includes 2 handpieces with 808nm wavelength, whereas the predicate has additional handpieces with other wavelengths. The indications for use in this submission are only for those with the Predicate's 810nm handpiece
Laser Contact	Sapphire, AL203	Sapphire, AL2O3	Same
Spot Sizes	20x9mm (1.8cm2), 34x14mm (4.75cm2)	20x9, 30x9, 30x17	1 same, 1 different. The spot size for the Eneka Pro XL handpiece is identical to the predicate. The dimension of the 2XL handpiece is nearly identical to the predicate. The dimension very slightly, but the total area is within .5cm of the predicate.
Fluence	40J/cm2	80 J/cm2	Different. Though the fluence of the predicate device is higher, this is not the actual fluence used in treatment (see next row)
Maximum fluence actually used (as per treatment protocols)	40J/cm2	43 J/cm2	Different. The fluence of the Eneka Pro is marginally lower than the predicate but

			functionally they are the same
Frequency	1-4Hz (Dynamic) 5-10Hz (Fast Dynamic)	UP TO 3 Hz (static) 5 – 10 Hz (dynamic)	Same. The overall frequency range of the two devices are the same.
Pulse Duration	5ms-400ms	3 – 400 ms/ AUTO (3 ms)	Different. The predicate's low end pulse duration is marginally higher than the Eneka Pro but it does not impact treatment.
Treatment Mode	Dynamic and Fast Dynamic	Static and Dynamic	Same. The Eneka Pro's Dynamic mode functions the same as the predicate's Static mode, and the Eneka Pro's Fast Dynamic mode function the same as the predicate's static mode. Details on their frequencies are in the table below. The difference are only in marketing terminology.
Tissue Cooling	Contact cooling system	Contact cooling system	Same.
Cooling Temperature	3 ºC	5ºC	Different.
User Interface	LCD Touchscreen	LCD Touchscreen	Same.
Pulsing Control	Finger Switch	Finger Switch	Same.
Configuration	Main unit and handpiece	Main unit, handpiece, and foot control (optional)	Same
Laser Classification	IV	IV	Same.
Power Supply	115 V a.c 50/60 Hz	Single Phase, 100-240V, 50-60Hz	Different.
Dimension	620 mm x 430 mm x 630 mm	1140 x 480 x 550 mm	Different.
Weight	32 Kg	75 Kg	Different.

Performance Testing

Verification and validation activities were successfully completed and establish that the Eneka Pro performs as intended. Testing included the following:

IEC 60601-1:2005 (Third Edition) + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests

IEC 60601-2-22: 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

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Conclusion

The Eneka Pro and Primelase Diode Lasers are nearly identical in the specifications. They have small differences in the design that do not impact the safety or effectiveness of the subject device, but only impact the user experience. The two devices can be considered substantially equivalent.