April 10, 2024

El.En. S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FL 50141
Italy

Re: K234057
Trade/Device Name: Nirvana
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: March 14, 2024
Received: March 14, 2024

Dear Paolo Peruzzi:

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: 2024.04.10 15:21:02 -04'00'

Tanisha Hithe
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)*
K234057

Device Name
Nirvana

Indications for Use *(Describe)*
The Nirvana device is indicated for hair removal and permanent hair reduction.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing 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.

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510(k) Summary

K234057

NIRVANA

Submitter:

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Contact:

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Date Summary Prepared:

March 22nd, 2024

Device Trade Name:

NIRVANA

Common Name:

Medical Laser

Regulation Number:

21 CFR 878.4810

Regulation Name:

Laser Surgical Instrument for use in General and Plastic and in Dermatology

Regulatory Class:

Class II

Product Code:

GEX

Predicate Devices:

Primary predicate:	DEKA LUXEA (K192539)
Reference predicate:	ASCLEPION MeDioStar (K192483)

Device Description:

The NIRVANA is a diode laser device indicated for hair removal and permanent hair reduction. The device is provided with two different handpieces that deliver the laser energy to the patient.
The NIRVANA electrical specifications are: 100-115V~, 50/60Hz, 1600VA.

Indications for Use:

The Nirvana device is indicated for hair removal and permanent hair reduction.

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

Comparison with The Predicate Device:

The NIRVANA is as safe, as effective, and performs as well as the legally marketed predicate devices (K192539 and K192483):

Device Trade Name	Proposed Device **Nirvana**	Predicate Device **DEKA LUXEA VIVID LASER handpiece** (K192539)	Reference Device **ASCLEPION MeDioStar** (K192483)	Comment
Indications for Use	Indicated for hair removal and permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of benign vascular lesions. Intended for the treatment of benign pigmented lesions. Intended for hair removal, permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months.	Subset of predicate device and reference device
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Product Code	GEX	GEX	GEX	Identical
Device Type	Diode Laser	Diode laser	Diode Laser	Identical

Device Trade Name	Proposed Device **Nirvana**	Predicate Device **DEKA LUXEA VIVID LASER handpiece** (K192539)	Reference Device **ASCLEPION MeDioStar** (K192483)	Comment
Wavelength	809 ± 6 nm	808 ± 10 nm	760± 10 nm 808± 10 nm 940 ± 10 nm	Same as predicate device, subset of reference device
Handpiece Spot Size	12x24 mm 12x12mm	10x12 mm	Spot size at 808± 10 nm: 10 x 10 mm 15 x 10 mm 30 x 10 mm 31.6 x 31.6 mm	Larger than predicate device, within the ranges of reference device
Max Fluence	40 J/cm^2	40 J/cm^2	Max fluence at 808± 10 nm: 60 J/cm^2	Identical to predicate device, within the range of reference device
Pulse Duration	Up to 200 ms	Up to 200 ms	Up to 400 ms	Identical to predicate device, within the range of reference device
Max output peak power	1800W	900W	4200W	Higher than predicate device, within the range of reference device
Max output average power	174W	81W	250W	Higher than predicate device, within the range of reference device
Pulse Repetition Rate (Hz)	Single shot to 10 Hz	Single shot to 10 Hz	Up to 20Hz	Identical to predicate device, within the range of reference device

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the NIRVANA device, according to the following standards:

- ANSI AAMI ES60601-1Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-22: Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1: Safety of laser products - Part 1: Equipment classification and requirements.

Software Validation and Verification Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

Conclusion:

On the basis of the comparison with the predicate device and on the non-clinical performance data, we can conclude that NIRVANA is as safe, as effective, and performs as well as the legally marketed predicate devices (K192539 and K192483).

Additional Information:

None.