December 20, 2021

Candela Corporation
Rina Ordonez
Senior Regulatory Affairs Specialist
251 Locke Drive
Marlborough, Massachusetts 01752

Re: K212492
Trade/Device Name: Frax 1940 for Nordlys and Frax Pro Systems
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: August 6, 2021
Received: August 9, 2021

Dear Rina Ordonez:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212492

Device Name
Frax 1940 for Frax Pro and Nordlys Systems

Indications for Use *(Describe)*
Nordlys system is intended to be used in dermatology as listed below:
Nordlys System + Intense pulse light applicators:
* Permanent Hair Reduction (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 regimen) (overall 600 - 950 nm).
* Treatment of Telangiectasias (530-750 nm or 555-950 nm)
* Treatment of Port Wine Stains (530-750 nm or 555-950 nm)
* Treatment of Benign Pigmented Lesions (eg Mottled Pigmentation, Ephelides) and Benign Vascular Lesions (eg Diffuse Redness) (530-750 nm or 555-950 nm)
* Treatment of Rosacea (530-750 nm or 555-950 nm)
* Treatment of Poikiloderma of Civatte (530-750 nm or 555-950 nm)
* Treatment of Benign Epidermal Pigmented Lesions (eg Solar Lentigines) (400-720 nm)
* Treatment of Inflammatory Acne Vulgaris (530-750 nm)

Nordlys System + Nd:YAG Laser (1064 nm):
*Treatment of Leg Vessels (0.1-3.0 mm diameter).
* Treatment of Benign Vascular Lesions.
* Treatment of Venous Lakes.
* Treatment of Port Wine Stains.
* Treatment for Clear Nail defined as: Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).
* Treatment of benign cutaneous lesions, such as warts.
Podiatry (ablation, vaporization, incision, and coagulation of soft tissue), including:
- Matrixectomy
- Periungal and subungal warts
- Plantar warts.

Nordlys System + Frax 1940 Laser (1940 nm):
* The Frax 1940 is indicated for use in dermatological procedures requiring the coagulation of soft tissue and for skin resurfacing procedures.
Frax 1940 is indicated for treatment of benign pigmented lesions, such as but not limited to lentigines (age spots), solar lentigines (sunspots), and ephelides (freckles) for Fitzpatrick Skin Types I-IV.

Nordlys System + Frax 1550 Laser (1550 nm):
*The Frax 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

Frax Pro system (Ydun) is intended to be used in dermatology, as listed below:
* The Frax 1940 is indicated for use in dermatological procedures requiring the coagulation of soft tissue and for skin resurfacing procedures.
Frax 1940 is indicated for treatment of benign pigmented lesions, such as but not limited to lentigines (age spots), solar lentigines (sunspots), and ephelides (freckles) for Fitzpatrick Skin Types I-IV.

Frax Pro System + Frax 1550 (1550 nm)
*The Frax 1550nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

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.

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510(k) SUMMARY

K212492

Frax 1940 for Nordlys & Frax Pro Systems

This summary of 510(k) submitted in accordance with the requirements of 21 CFR 807.92.

1. DATE PREPARED

December 17, 2021

2. APPLICANT NAME

Candela Corporation
251 Locke Drive
Marlborough MA 01752
USA

3. OFFICIAL CORRESPONDENT

Rina Ordonez
Sr. Regulatory Affairs Specialist
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251 Locke Drive
Marlborough MA 01752 USA
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4. PRODUCT INFORMATION

Name of Device: Frax 1940 for Nordlys & Frax Pro Systems

Common/Usual Name: Intense Pulse Light (IPL) & Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR 878.4810).

Device Classification: Class II (per CFR 870.1250)

Product Code: GEX

5. LEGALLY MARKETED PREDICATE DEVICE FOR CLAIMED EQUIVALENCE:

Predicate Device: Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun (K192951)
Co-predicate Device: Fraxel Dual 1550/1927 Laser System (K130193)

6. DEVICE DESCRIPTION:

The Frax 1940 applicator is used with the Nordlys and Frax Pro system (previous called Ydun).
The Nordlys and Frax Pro systems consist of a console containing power unit and control electronics with control and display panel, including software. The Frax 1940 applicator connects to the systems and has built in Laser diodes emitting 1940 nm light in a fractional pattern.

7. INTENDED USE AND INDICATIONS FOR USE STATEMENT:

Nordlys system is intended to be used in dermatology as listed below:
Nordlys System + Intense pulse light applicators:
* Permanent Hair Reduction (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 regimen) (overall 600 - 950 nm).
* Treatment of Telangiectasias (530-750 nm or 555-950 nm)
* Treatment of Port Wine Stains (530-750 nm or 555-950 nm)
* Treatment of Benign Pigmented Lesions (eg Mottled Pigmentation, Ephelides) and Benign Vascular Lesions (eg Diffuse Redness) (530-750 nm or 555-950 nm)
* Treatment of Rosacea (530-750 nm or 555-950 nm)
* Treatment of Poikiloderma of Civatte (530-750 nm or 555-950 nm)
* Treatment of Benign Epidermal Pigmented Lesions (eg Solar Lentigines) (400-720 nm)
* Treatment of Inflammatory Acne Vulgaris (530-750 nm)

Nordlys System + Nd:YAG Laser (1064 nm):
*Treatment of Leg Vessels (0.1-3.0 mm diameter).
* Treatment of Benign Vascular Lesions.
* Treatment of Venous Lakes.
* Treatment of Port Wine Stains.
* Treatment for Clear Nail defined as: Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).
* Treatment of benign cutaneous lesions, such as warts.
Podiatry (ablation, vaporization, incision, and coagulation of soft tissue), including:
- Matrixectomy
- Periungal and subungal warts
- Plantar warts.

Nordlys System + Frax 1940 Laser (1940 nm):
* The Frax 1940 is indicated for use in dermatological procedures requiring the coagulation of soft tissue and for skin resurfacing procedures.

Frax 1940 is indicated for treatment of benign pigmented lesions, such as but not limited to lentigines (age spots), solar lentigines (sunspots), and ephelides (freckles) for Fitzpatrick Skin Types I-IV.

Nordlys System + Frax 1550 Laser (1550 nm):
*The Frax 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

Frax Pro system (Ydun) is intended to be used in dermatology, as listed below:

Frax Pro System + Frax 1940 (1940 nm)
*The Frax 1940nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.
Frax 1940 is indicated for treatment of benign pigmented lesions, such as but not limited to lentigines (age spots), solar lentigines (sunspots), and ephelides (freckles) for Fitzpatrick Skin Types I-IV.

Frax Pro System + Frax 1550 (1550 nm)
*The Frax 1550nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

8. TECHNOLOGICAL COMPARISON:

The subject device Frax 1940 for Nordlys and Frax Pro and its predicate device Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun (K192951) are identical in the design, technology and biological characteristics of the applicator and consoles.

The Frax 1940 and 1927nm part of the co-predicate device Fraxel Dual 1550/1927 Laser System are similar in their principal of operation/mechanism of action. The interaction between laser light and the different skin tissue component is dictated by the optical absorbance of the tissue at the specified wavelength, the optical power and pulse duration.

The Frax 1940 and 1927nm part of the co-predicate device Fraxel Dual 1550/1927 Laser System are both handheld scanning applicators with comparable design, using active air cooling, with comparable wavelength and comparable technological specifications including maximal pulse energy, maximal pulse duration and maximal microspot size and density.

9. PERFORMANCE DATA:

Performance Standards:

The Frax 1940 with Nordlys and Frax Pro Laser systems has been tested according to and comply with:

- IEC 60601-1, 3rd Edition 2005+A1:2012: Medical electrical equipment-- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements and tests.
- EN 60825-1, Edition 3.0 2014 Safety of laser products – Equipment classification and requirements.
- IEC 60601-2-22 Edition 3.0, 2007 Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment.

Clinical Testing

Two clinical studies were conducted on the Frax 1940 to support the new indications of benign pigmented lesions.

The results of the clinical studies demonstrated favorable safety and effectiveness profile for the Frax 1940 nm laser system for the indicated use for benign pigmented lesions removal after 1-3 treatment sessions.

10. SUBSTANTIAL EQUIVALENCE COMPARISON:

When comparing Frax 1940 to the predicate device Ellipse Frax 1940 (K192951) and co-predicate device Fraxel Dual 1927 Laser System (K130193), the additional indications for use do not raise new issues of safety and effectiveness.

The Frax 1940 with Nordlys and Frax Pro is substantially equivalent, in terms of technological characteristics, performance, intended use/ indications for use, to the predicate device Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun (K192951) and the co-predicate device Fraxel Dual 1550/1927 Laser System (K130193).