March 26, 2020

Ellipse A/S
Ole Kofod
RA Manager
Agern Alle 11
Hoersholm, DK-2970 DK

Re: K192951
Trade/Device Name: Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun
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, ONG
Dated: February 20, 2020
Received: February 26, 2020

Dear Ole Kofod:

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,

Jessica Mavadia-Shukla, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192951

Device Name
Ellipse Frax 1940 for Ellipse Ydun and Ellipse Nordlys

Indications for Use *(Describe)*
Ellipse Nordlys system is intended to be used in dermatology, as tabled below:
* Permanent Hair Reduction (defined as teh 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)(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, Ephilides) 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 Lentigo Solaris)(400-720 nm)
* Treatment of Inflammatory Acne Vulgaris (530-750 nm)

Ellipse Nordlys + 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.

Ellipse Nordlys + 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.

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

Ellipse Ydun system is intended to be used in dermatology, as tabled below:
Ellipse Ydun + Frax 1550, (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.

Ellipse Ydun + Frax 1940, (1940 nm)
*The Frax 1940 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general 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) Submission – K192951

Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun

Substantial Equivalence Comparison - Summary

This *510(k) summary* is submitted in accordance with the requirements of 21 CFR Part 807.87(h) and Part 807.92.

Submitter Information:

Date of the summary:	26 March 2020
Submitted by/manufacturer:	***Ellipse A/S*** (Establishment Registration no. **3005112495**) Agern Alle 11 2970 Hoersholm, Denmark Tel: + 45 4576 8808 Cell.: +45 2395 8055
Contact person:	Ole Kofod

Device Identification:

Device Trade Name 1**:**	**Ellipse Frax 1940** for Ellipse Ydun and Ellipse Nordlys.
Device Model number 1:	**9APP7908**.
Common Name:	Intense Pulsed Light (IPL) & Laser.
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810).
Device classification:	Class II (per 21 CFR 870.1250).
Product code:	GEX

Predicate Devices:

Predicate device legally marketed to which Ellipse A/S claims substantial equivalence:	Fraxel Dual 1550/1927 Laser System (K130193). Solta Medical, Inc. 25881 Industrial Blvd., Hayward, CA 95545, USA.

Description of *Ellipse Frax 1940 applicator (hand piece)*:

The Frax 1940 applicator is used with the Ellipse Nordlys (K150907 and K161162) and Ellipse Ydun (K180406).
The Nordlys and Ydun systems consists of a console containing power unit and control electronics with control and display panel, including software. The Frax 1940 applicator connects to the system and have built in Laser diodes emitting 1940 nm light in a fractionated pattern.
The mode of action is delivering a series of light pulses in a row of up to 10 mm as the applicator is moved across the skin. This leaves a pattern of micro dots (Micro Thermal Zone) of irradiated skin, typically in the order of 100 MTZ/cm2. Due to the area of the damaged skin in each MTZ, a certain percentage of the covered skin is affected, and this is referred to as the Coverage (percentage) of the treatment.
The control of pulses as the applicator is moved is by a magnetic motion sensor embedded in the roller that also acts as skin distance controlling device.
The motion detection and the control of the laser diodes is done in a micro controller embedded in the handpiece.
The materials used are the same as the predicate device Frax 1550 (aluminum and ABS), and the applicator is intended to be in contact with the patient for 15-30 minutes.
The system is intended to be used in healthcare facilities and hospital environments.

Intended Use/Indications for Use:

Ellipse Ydun **system is intended to be used in dermatology, as tabled below:**

Using 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.
- **Using Frax 1940 Laser, (1940 nm):**
  The Frax 1940 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

Ellipse Nordlys system is intended to be used in dermatology, as tabled below:

- 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 regime) (overall 600-950nm).
- Treatment of Telangiectasias (530-750nm or 555-950nm).
- Treatment of Port Wine Stains (530-750nm or 555-950nm).
- Treatment of Benign Pigmented Lesions (eg Mottled Pigmentation, Ephilides) and Benign Vascular Lesions (eg Diffuse Redness) (530-750nm or 555-950nm).
- Treatment of Rosacea (530-750nm or 555-950nm).
- Treatment of Poikiloderma of Civatte (530-750nm or 555-950nm).
- Treatment of Benign Epidermal Pigmented Lesions (eg Lentigo Solaris) (400-720nm).
- Treatment of Inflammatory Acne Vulgaris (530-750nm).

Using 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, excision, and coagulation of soft tissue), including:
  - Matrixectomy.
  - Periungal and subungal warts

- Plantar warts.

Using 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.

- **Using Frax 1940 Laser, (1940 nm):**
  The Frax 1940 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

Technological Comparison

The Frax 1940 and the 1927 nm part of the predicate Fraxel Dual 1550/1927 Laser System are largely the same. 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.
Treatment for both Lasers are performed with the handheld scanning applicator of comparable design, using active air cooling and using comparable wavelength.
Overall, the minor differences in technical characteristics do not indicate a difference in clinical safety and performance.
No new technology is used for the Frax 1940, which is based on the CE- and FDA- cleared (K161162 and K180406) sister applicator Ellipse Frax 1550.

Assessment of performance data

The substantial equivalence to the predicate device is established based on tests and analysis both in terms of clinical and nonclinical evaluations.

The nonclinical evaluation has been focused on the beam diameter and the wavelength of the Frax 1940 and the Fraxel 1927. The beam diameters have been compared based on measurement of the Frax 1940 and on the labeling of the Fraxel 1927, and the results are that the beams are comparable, with the Frax 1940 having a smaller beam diameter than the predicate device. Regarding the differences in wavelength between the 2 devices, a theoretical analysis has been established showing negligible difference in chromophore absorption at the 2 wavelengths, supported by a statement from a Professor of Dermatology. On all other parameters, the devices are equivalent. Furthermore, the Energy levels as well as the Coverage are equivalent for the 2 devices.

In terms of clinical testing, the tissue damage and healing process has been tested. A prospective, controlled, in-vivo histological healing response study of human abdominal skin following the FRAX 1940 laser exposure has been conducted on 3 subjects. The study showed complete healing with no significant adverse events. The healing was complete after 7 days for exposure of 5 mJ and 34 days post treatment for 20 mJ. Furthermore, the study did show good tolerance to angulation of the applicator during treatment. The immediate effect following Laser exposure was test areas typically exhibiting mild to moderate edema and erythema which resolved by the next study visit 1 to 7 days afterwards.
Post Inflammatory Hyperpigmentation (PIH) was noted in one subject and only in areas exposed with the 5 mJ energy setting. These areas were accidentally exposed with a coverage of 77.9%, which is significantly higher than the recommended settings for off-face treatment in Fitzpatrick skin type I-III of 20-35%

Based on the evaluations and tests, and on the comparison matrix enclosed in this filing, showing that the parameters for Frax 1940 and the predicate device are equivalent, it is concluded that the Frax 1940 is as safe and effective as the predicate device, Fraxel Dual 1550/1927.

Performance Standards:

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

- US FDA 21 CFR 1040.10 and 1040.11 for class IV Laser Products.
- IEC 60601-1 3rd edition, UL 60601-1 and CSA C22.2 No. 601.1.
- IEC 60825-1 and IEC 60601-2-22.
- IEC 60601-1-2.
- Complies with the European Medical Device Directive 93/42/EEC (Annex II).
- Manufactured under ISO13485 Quality Management System certified by Presafe/DGM and QMI and also complies with the US FDA 21CFR Part 820.

Substantial Equivalence conclusion:

The *Ellipse Frax 1940* applicator is substantially equivalent, in terms of technological characteristics, performance, intended use/indications for use, to the predicate device (K130193) listed on page 1 of this document.

The *Ellipse Frax 1940* applicator has been evaluated and compared to the above-mentioned predicate device and applications, parameters, and intended use/indications for use, as explained above, and have been judged to be substantially equivalent to the mentioned predicate device.