DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 16, 2016

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

Re: K161162
Trade/Device Name: Frax 1550 For Ellipse Nordlys/ Ellipse Nordlys+, Ellipse Sirius, Ellipse Infinity, Ellipse Mjolner, Ellipse Nordlys Ultra
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 15, 2016
Received: August 18, 2016

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. 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 Part 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161162

Device Name

Ellipse Nordlys

Indications for Use *(Describe)*

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.

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 – K161162

Ellipse Frax 1550 for Nordlys

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:	13 September 2016
Submitted by/manufacturer:	***Ellipse A/S*** (Establishment Registration no. **3005112495**) Agern Alle 11 2970 Hoersholm, Denmark Tel: + 45 4576 8808 Fax: + 45 4517 6851
Contact person:	Ole Kofod

Device Identification:

Device Trade Name 1:	***Frax 1550 for Ellipse Nordlys*** (with IPL and Nd:YAG hand pieces/applicators).
Device Model number 1:	**9APP7829 for 9SYS7751.**
Alternative Device Trade Name and Model:	Ellipse Sirius system 9SYS7773 Ellipse Infinity system 9SYS7774 Ellipse Mjølner system 9SYS7775 Ellipse Nordlys+ system 9SYS7776 Ellipse Nordlys ultra system 9SYS7777
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 devices (for other than Frax 1550) legally marketed to which Ellipse A/S claims substantial equivalence:	Ellipse Nordlys (K150907) Ellipse A/S Agern Alle 11 DK-2970-Hørsholm, Denmark
Predicate devices (for Frax 1550) legally marketed to which Ellipse A/S claims substantial equivalence:	Palomar Icon Aesthetic System (K142376) Cynosure Inc. 5 Carlisle Road Westford, MA 01886, USA Fraxel Dual (K130193) Solta medical, Inc. 25881 Industrial Blvd. Hayward, CA 94545, USA

Lutronic Mosaic (K080932)
Lutronic Coorporation
#403-2,3,4, Ilsan Technotown
1141-1Baeksok-Dong, Ilsan-Gu
Goyang-Si, Gyeonggi-Do, 410-722
Republic of Korea

Lumenis ResurFX (K130028)
Lumenis Ltd.
31 Haavoda St.
Binyamina, IL 30500,
USA

Description of Ellipse *Nordlys with associated applicators (hand pieces)*:
Ellipse Nordlys is an Intense Pulsed Light (IPL) and Laser system (Nd:YAG 1064 nm and Fractional 1550 nm) used for long-term removal of unwanted hair; for treatment of sun-damaged skin, including uneven pigmentation, age spots, large pores, diffuse redness, and for the treatment of telangiectasias, port wine stains, rosacea, poikiloderma of civatte and inflammatory acne in the area of dermatology.
The systems consist of a console containing power unit and control electronics with control and display panel including software.
IPL Applicators/hand-pieces are connected to the systems in order to generate light energy for treatment in the waveband 400 nm – 950 nm.
Additionally a Nd:YAG hand piece (1064 nm) and a Fractional (1550 nm) hand piece can be connected to the *Ellipse Nordlys* for treatment of: Vascular lesions as stated below under Intended Use/Indications for Use for the Nd:YAG and fractional treatments for non-ablative skin resurfacing for Frax 1550 as stated below.

Intended Use/Indications for Use:

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).

<u>Using Nd:YAG Laser, (1064 nm):</u>

- Treatment of Leg vessels (0.1 -3.0mm 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.

<u>Using Frax 1550 Laser, (1550 nm):</u>

- 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.

Performance Standards utilized

The ***Ellipse Nordlys*** Intense Pulsed Light (IPL) and Laser system 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 60601-2-57.
- 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.

Performance Data

Testing certificates by UL International and Delta according to above listed *Performance Standards* were provided which demonstrates that Ellipse Nordlys with the listed applicators/handpieces utilize technical parameters which are as safe and effective as the predicate devices.

Substantial Equivalence conclusion:

The *Ellipse Nordlys* system as regards its IPL and Nd:YAG applications is identical to the previously cleared *Ellipse Nordlys* system (K150907).
An *Ellipse Frax 1550* hand piece has now been added to the system (included in this application K161162).
The *Ellipse Frax 1550* hand piece has been evaluated and compared to the 1550nm hand piece of the predicate systems Cynosure/Palomar Icon® 1540 nm (K142376), Fraxel Dual® 1550 nm hand piece (K130193), Lumenis ResurFX (K130028) and Lutronic Mosaic (K080932).
Ellipse Frax 1550 is found to be substantial equivalent to these with respect to clinical, technical and biological issues of these systems.

The default start settings for the Frax 1550 are based on settings used in the most relevant clinical investigations found to be safe and effective in the Ellipse literature study (RA18704, appendix 2) and equivalent to what are used as standard settings for the same treatments for Frax SR1550 (K130193) and Icon Lux1540 (K142376).

It is hereby proven that the chosen default parameters for Ellipse Frax1550 both are equivalent to settings already shown to be safe an effective by FDA cleared equipment (predicate devices) as well as being inside the mentioned consensus parameter recommendations. Furthermore, it is proven that the possible maximum energy settings for the individual treatments are inside what have already been considered to be safe and effective.

The new, added fractional application, *Non-ablative Skin Resurfacing*, is found to be substantially equivalent to the same application of the mentioned predicate devices.

Based on this analysis of the overall performance characteristics of the mentioned predicate devices Ellipse A/S believes that no significant differences exist. The ***Ellipse Nordlys*** system, now with the ***Ellipse Frax 1550*** Laser applicator/hand piece added, should not raise new issues of safety and effectiveness and are judged to be substantially equivalent to the mentioned predicate devices.

(Signature)

Ole Kofod
(Typed Name)

13-September-2016
(Date)

K161162
(Premarket Notification 510(K) number).