DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2014

Ellipse A/S
Mr. Ole Kofod
Quality Assurance/Regulatory Affairs Manager
Agern Allé 11
DK-2970 Hoersholm
Denmark

Re: K140670
Trade/Device Name: *Ellipse I2PL+* (with IPL hand pieces/applicators), *Ellipse MultiFlex+*(with IPL and Nd:YAG hand pieces/applicators)
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: ONF, GEX
Dated: September 5, 2014
Received: September 11, 2014

Dear Mr. 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 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 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" (21CFR 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,

David Krause -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)*
K140670

Device Name
Ellipse I2PL+
Ellipse MultiFlex+

Indications for Use *(Describe)*
Ellipse I2PL+ and Ellipse MultiFlex+ systems are intended to be used in dermatology, as tabled below:
- Permanent hair reduction (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) (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, (1064nm) (Ellipse MultiFlex+ system, only):
- Treatment of Leg vessels (0.1 -3.0mm diameter).
- Treatment of Benign Vascular Lesions.
- Treatment of Venous Lakes.
- Treatment of Port Wine Stains.
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 – Section 3 Rev 3

Ellipse I²PL+
Ellipse MultiFlex+

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:	28 August 2014
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**:**	***Ellipse I²PL+*** (with IPL hand pieces/applicators).
Device Model number 1:	9ESL7228.
Device Trade Name 2**:**	***Ellipse MultiFlex+*** (with IPL and Nd:YAG hand pieces/applicators).
Device Model number 2:	9ESF7496.
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 legally marketed to which Ellipse A/S claims substantial equivalence:	***Ellipse I²PL*** (K060516). Ellipse A/S Agern Alle 11, DK-2970 Hoersholm, Denmark. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). ***Ellipse MultiFlex*** (K081408). Ellipse A/S Agern Alle 11, DK-2970 Hoersholm, Denmark. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). ***StarLux™ Pulsed Light System*** (K041086). Palomar Medical Technologies, Inc., 82 Cambridge Street, Burlington, MA 01803, USA. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). ***Icon™*** Palomar Medical Technologies, Inc., 82 Cambridge Street, Burlington, MA 01803, USA. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). ***Genesisplus Laser System™*** Cutere, Inc., 3240 Bayshore Blvd., Brisbane, CA94005, USA.

Description of Ellipse I2PL+ and Ellipse MultiFlex+:

Ellipse I²PL+ and *Ellipse Multiflex+* are identical Intense Pulsed Light (IPL) systems 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 handpiece (1064 nm) can be connected to the *Ellipse MultiFlex+* for treatment of vascular lesions as stated below under Intended Use/Indications for Use.

Intended Use/Indications for Use:

Ellipse I2PL+ and Ellipse MultiFlex+ systems are 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, (1064nm) (Ellipse MultiFlex+ system, only):
- 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.).

Performance Standards

The *Ellipse I²PL+* and *Ellipse MultiFlex+* Intense Pulsed Light (IPL) and Laser systems have 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.

Substantial Equivalence conclusion:

The *Ellipse I²PL+* and *Ellipse MultiFlex+* systems are substantially equivalent in terms of technological characteristics, performance, intended use/indications for use to the predicate devices listed on page 1 of this document.

The *Ellipse I²PL+* and *Ellipse MultiFlex+* has been evaluated and compared to the above mentioned predicate systems and to their application modules. The *Ellipse I²PL+* and *Ellipse MultiFlex+* as far as the identical modules, applications, parameters, and intended uses/indications are concerned, have been judged to be substantially equivalent to the mentioned predicate devices. Based on this analysis of the overall performance of the mentioned predicate devices Ellipse A/S believes that no significant differences exist. The *Ellipse I²PL+* and *Ellipse MultiFlex+* systems should not raise new issues of safety or effectiveness.