March 15, 2018

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

Re: K180406
Trade/Device Name: 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
Dated: February 9, 2018
Received: February 14, 2018

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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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)*
K18xxxx (TBD) K180406

Device Name

Ellipse Ydun

Indications for Use *(Describe)*

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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary – K180406 – Section 3

Ellipse Ydun

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:	15 March 2018
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 Ydun*** (with Frax 1550 hand piece/applicator).
Device Model number 1:	**9SYS7852**.
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:	Ellipse Nordlys with Frax 1550 (K161162) Ellipse A/S Agern Alle 11 DK-2970-Hørsholm, Denmark

Description of *Ellipse Ydun with associated Frax 1550 applicator (hand piece)*:

Ellipse Ydun is a platform/console capable of driving the ***Ellipse Frax 1550*** applicator, which is a 1550 nm Laser diode-based applicator cleared by FDA under K161162.
The ***Ydun*** system consists of a console containing power unit and control electronics with control and display panel, including software. The Frax 1550 applicator connects to the system and have built in Laser diodes emitting 1550 nm light in a fractionated pattern.

Intended Use/Indications for Use:

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

- Ydun is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

Technological Comparison

Subject device, ***Ellipse Ydun***, is identical to the predicate device in that the Frax 1550 applicator/handpiece being used is the same as used by the predicate device and the ***Ellipse Ydun*** console driving the Frax 1550 is of the same technological design.

Performance Standards:

The ***Ellipse Ydun*** 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 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 Ydun* system with *Ellipse Frax 1550* applicator is substantially equivalent, in terms of technological characteristics, performance, intended use/indications for use, to the predicate device (K161162) listed on page 1 of this document.
The *Ellipse Ydun* system has been evaluated and compared to the above mentioned predicate system and applications, parameters, and intended use/indications for use, and have been judged to be substantially equivalent to the mentioned predicate device.