510(k) Summary

Ellipse A/S

K081408

Ellipse MultiFlex with Nd:YAG handpiece

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

A. Contact information and device identification:

OCT 17 2008

Date of the summary:	16 May 2008
Submitted by/manufacturer:	Ellipse A/S Agern Alle 11 2970 Hoersholm, Denmark Tel: + 45 4576 8808 Fax: + 45 4517 6851
Contact person:	Ole Kofod
Device Trade Name:	*Ellipse MultiFlex* (with IPL and Nd:YAG handpieces).
Device Model number:	9ESF7496 system (with 9APP7472 Laser handpiece).
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.
Product code:	GEX
Predicate devices legally marketed to which Ellipse A/S claims substantial equivalence:	*Multi-Spot Nd:YAG* (K060448) manufactured by Lumenis Inc., 2400 Condensa Street, Santa Clara, CA 95051, USA. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). *Alma Harmony long pulsed Nd:YAG* (K033946) manufactured by MSq(M2) Ltd., 7 Haeshel St., P.O.B. 3021, Caesarea Industrial park, 38900 Israel. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). *Lux1064* (K041879) manufactured by 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)). *Ellipse Flex PPT* (K052688) manufactured by Ellipse A/S, Agern Alle 11, DK-2970 Hoersholm, Denmark, as far as all IPL applications concerns. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)).

B. Description of *Ellipse Multiflex*:

Ellipse Multiflex is an Intense Pulsed Light (IPL) system 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 and inflammatory acne in the area of dermatology.
The system consists of a console containing power unit and control electronics with control and display panel including software.
IPL Applicators/hand-pieces are connected to the system in order to generate light energy for treatment in the waveband 400 nm – 950 nm.
The above was cleared under K052688.
Additionally a Nd:YAG handpiece (1064 nm) can be connected to the *Ellipse MultiFlex* for treatment of vascular lesions as stated under Intended Use.

C. Intended Use:

Ellipse MultiFlex is intended for use in dermatology.

Ellipse MultiFlex used with *IPL applicators* (9APP7133, 7116, 7114, 7134, 7212, 7377, 7213):

- Hair removal (permanent hair reduction).
- Treatment of benign pigmented lesions (including, but not limited to solar lentigines, ephilides, mottled pigmentation) and benign vascular lesions (including but not limited to diffuse redness, telangiectasias, port wine stains).
- Treatment of inflammatory acne.

Ellipse MultiFlex used with *Nd:YAG applicator* (9APP7472):

- Treatment of leg vessels (0.1 – 3.0 mm diameter).

D. Performance Standards

The *Ellipse MultiFlex* Intense Pulsed Light (IPL) and Laser system has been tested according to and complies with:

- US FDA 21 CFR 1040.10 and 1040.11 for class IV Laser Products.
- IEC 60601-1, 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 DGM and QMI.

E. Substantial Equivalence conclusion:

The *Ellipse MultiFlex* system is substantially equivalent in terms of technological characteristics, performance, intended use/indications for use to the predicate devices listed on page 1 of this document.
All the stated intended uses of *Ellipse MultiFlex* with *Nd:YAG* has earlier been investigated and cleared by FDA for equipment which the performed comparison has shown to be substantially equivalent to regarding the applications in question.
The IPL Intended Use applications, as already cleared under K052688 for *Ellipse Flex PPT,* is maintained for the *Ellipse MultiFlex* used with IPL handpieces/applicators. The system platform remains. *Ellipse MultiFlex* is the next generation of the *Ellipse Flex PPT* which incorporates a Nd:YAG handpiece in addition to the IPL handpieces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ellipse A/S
% Ole Kofod
Agern Allé 11
DK-2970 Hørsholm
Denmark

OCT 17 2008

Re: K081408
Trade/Device Name: Ellipse MultiFlex
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 2, 2008
Received: September 3, 2008

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.

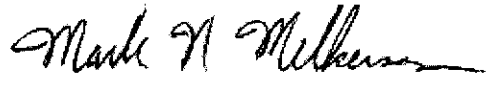
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification

Device Name: **Ellipse MultiFlex**

K081408

Indications for Use:

Ellipse MultiFlex is intended for use in dermatology.

Ellipse MultiFlex used with *IPL applicators* (9APP7133, 7116, 7114, 7134, 7212, 7377, 7213):

- Hair removal (permanent hair reduction).
- Treatment of benign pigmented lesions (including, but not limited to solar lentigines, ephilides, mottled pigmentation) and benign vascular lesions (including but not limited to diffuse redness, telangiectasias, port wine stains).
- Treatment of inflammatory acne.

Ellipse MultiFlex used with *Nd:YAG applicator* (9APP7472):

- Treatment of leg vessels (0.1 – 3.0 mm diameter).

The Indications for Use for *Ellipse MultiFlex* are:

Application	Treatment Variable	Fitzpatrick Skin Type					
		1	2	3	4	5	6
Hair Removal HR Applicator HR-S Applicator	Hair (Thin, Normal, Thick)	✓	✓	✓	✓	✓	⊘
Hair Removal HR-D Applicator	Hair (Thin, Normal, Thick)	✓	✓	✓	✓	✓	✓
Treatment of Benign Pigmented Lesions and Benign Vascular Lesions	Pigmentation / Vessel Size	✓	✓	✓	✓	⊘	⊘
Treatment of Telangiectasias	Vessel size (Thin, medium, thick)	✓	✓	✓	✓	⊘	⊘
Treatment of Port Wine Stains	Color (Red, blue)	✓	✓	✓	✓	⊘	⊘
Treatment of Individual Pigmented Lesions	Pigment Color	✓	✓	✓	✓	✓	⊘
Treatment of Inflammatory Acne		✓	✓	✓	✓	⊘	⊘
Key: ✓ Allowed; ⊘ Not Allowed							

Mark P Ogden -A

(Signature)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Ole Kofod
(Typed Name)

(Date)

510(k) Number K081408

(Premarket Notification 510(k) Number)

Prescription Use__X__ (21CFR 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)