MAY 15 2006

K 060516

510(k) SUMMARY

Danish Dermatologic Development A/S (DDD)
Ellipse I²PL dermatologic IPL system.

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:

Date of the summary:	1 February 2006
Submitted by/manufacturer:	Danish Dermatologic Development A/S Agern Alle 11 2970 Hoersholm, Denmark Tel: + 45 4576 8808 Fax: + 45 4517 6851
Contact person:	Ole Kofod
Device Trade Name:	Ellipse I²PL.
Device Model number:	9ESL7228-B02.
Common Name:	Intense Pulsed Light (IPL) system.
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 DDD claims equivalence:	*Ellipse I²PL* (K043255) manufactured by Danish Dermatologic Development 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 Flex PPT* (K052688) manufactured by Danish Dermatologic Development 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)).

B. Description of Ellipse I²PL:

Ellipse I²PL is an Intense Pulsed Light (IPL) system used for long-term removal of unwanted hair and 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.
Applicators/hand-pieces are connected to the system in order to generate light energy for treatment in the waveband 400 nm – 950 nm.

C. Intended Use of Ellipse I²PL:

Ellipse I²PL is intended for use in dermatology:

- 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.

The Indications for Use for *Ellipse I²PL* 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	✓	✓	✓	✓	⊘	⊘
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							

D. Comparison of *Ellipse I²PL* to predicate devices:

	Ellipse I²PL (B02)	**Ellipse Flex PPT**	**Ellipse I²PL (A01)**
510(k) reference	This submission	K052688	K043255
Technology/ Operation/ Device description	Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.	Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.	Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.
Intended Use	Hair removal and the treatment of benign pigmented and vascular lesions; Treatment of Inflammatory Acne.	Hair removal and the treatment of benign pigmented and vascular lesions; Treatment of Inflammatory Acne.	Hair removal and the treatment of benign pigmented and vascular lesions;
Energy spectrum	400-950 nm	400-950 nm	555-950 nm
Energy ouput/ setting	0-26 J/cm²	0-26 J/cm²	0-26 J/cm²
Pulse duration	1,5-100 ms	1,5-100 ms	5-55 ms
Applicator/hand-piece spot size	10 x 48 mm	10 x 48 mm	10 x 48 mm
Charge time/ repetion rate	1.5-2.0 s	1.5-2.0 s	1.5-2.0 s
Cooling method	Cooling handpiece by circulating water.	Cooling handpiece by circulating water.	Cooling handpiece by circulating water.
Device classification	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX

Conclusion:

The Ellipse I²PL (B02) has been evaluated and compared to its predicate systems (to Ellipse I²PL (A01) (manufactured by DDD), and Ellipse Flex PPT (manufactured by DDD)). The Ellipse I²PL (B02) system, as far as the identical modules, applications and intended uses are concerned, are identical to Ellipse I²PL (A01) and identical and substantially equivalent to the Ellipse Flex PPT with regards to technology as well as modules, applications and intended uses.

Based on this analysis of the overall performance characteristics of the mentioned predicate devices Danish Dermatologic Development A/S (DDD) concludes that no significant differences exist. The applications added to the original Ellipse I²PL system does not raise new issues of safety and effectiveness and is substantially equivalent to the mentioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

Danish Dermatologic Development A/S
c/o Mr. Ole Kofod
QA/RA Manager
Agern Alle 11
2970 Hoersholm, Denmark

Re: K060516
Trade/Device Name: Ellipse I^2PL
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: February 1, 2006
Received: February 27, 2006

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.

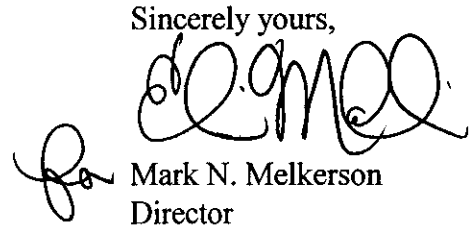
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use

510(k) number: **K060516**

Device Name: **Ellipse I^2PL**

Indications for Use:

The Intended Use for Ellipse I^2PL is:

Ellipse I^2PL is intended for use in dermatology:

- 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.

The Indications for Use for *Ellipse I^2PL* 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							

Prescription Use__X__ AND/OR Over-The-Counter Use____
(Part 21CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060516