FEB 2 4 2005

510(k) SUMMARY

K043255

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:	11 February 2005
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.
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:	*IPL™ Quantum* (K024093; K020839) 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)). *Skin Station™* (K030897) manufactured by Radiancy Inc., 40 Ramland Road South, Suite 10, Orangeburg, New York 10962,USA. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). *EsteLux™* (K020453) manufactured by Palomar Medical Technologies, Inc., 82 Cambridge Street, Burlington, MA 01803. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)).

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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 and diffuse redness 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 555 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 (diffuse redness). 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	✓	✓	✓	✓	⊘	⊘
Note: Patients with darker Fitzpatrick Skin Types (4 or above) or who are suntanned should **always** be treated with extra care and attention. **Key: ✓ Allowed; ⊘ Not Allowed**							

D. Comparison of Ellipse I²PL to predicate devices:

	Ellipse I²PL	**IPL™ Quantum**	**Skin Station™**	**EsteLux™**
510(k) reference	Current submission	K024093; K020839	K030897	K020453
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. Knob operation.	Intense Pulsed Light (IPL)/broad spectrum. Knob operation with display.
Intended Use	Hair removal and the treatment of benign pigmented and vascular lesions	Hair removal, treatment of tattoos, benign pigmented and benign vascular lesions	Hair removal and treatment of pigmented and vascular lesions	Hair reduction, treatment of facial and leg veins and vascular and benign pigmented lesions
Energy spectrum	555-950 nm	515-1200 nm *	400-1200 nm	470-1400 nm
Energy ouput/ setting	0-21 J/cm²	15-45 J/cm² *	3-10 J/cm²	12-40 J/cm²
Pulse duration	5-55 mS	2-16 mS (to 48 mS triple pulsed). *	10 and 35 mS	10-100 mS

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	Ellipse I²PL	IPL™ Quantum	Skin Station™	EsteLux™
510(k) reference	Current submission	K024093; K020839	K030897	K020453
Applicator/hand-piece spot size	10 x 48 mm	8 x 34 mm	22 x 55 mm and 35 x 12 mm	16 x 46 mm,12 x 28 mm,12 x 12 mm, 10 x 15 mm
Charge time/ repetion rate	1.5-2.0 Sec.	2 Sec.	N/A	1 Sec.
Cooling method	Cooling handpiece by circulating water.	Skin cooling components integrated in hand piece.	N/A	Skin cooling possible with Cool Roller™
Device classification	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX

* See conclusion.

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Conclusion:

IPL™ Quantum has a broader range of applications than Ellipse I²PL. IPL™ Quantum may be updated with a Laser module for vascular treatment applications in addition to the IPL modules. Ellipse I²PL does not employ a Laser module, only IPL. Ellipse I²PL thus utilizes a subset of the IPL™ Quantum applications.

SkinStation™ has identical range of applications as Ellipse I²PL, and the intended use and the performance is substantially equivalent.

EsteLux™ has a broader range of applications than Ellipse I²PL, the intended use for Ellipse I²PL is covered by the EsteLux™ and the performance is substantially equivalent.

The systems and identical application modules utilized by IPL™ Quantum (Lumenis, Inc.), Skin Station™ (Radiancy Ltd.) , and EsteLux™ (Palomar) have been evaluated and compared to Ellipse I²PL. The Ellipse I²PL system, as far as these identical modules, applications and intended uses are concerned, are judged to be substantially equivalent to the IPL™ Quantum (predicate device cleared in K024093, K020839), SkinStation™ (predicate device cleared in K030897), and EsteLux™ (predicate device cleared in K991935, K984110).

Based on this analysis of the overall performance characteristics of the mentioned predicate devices Danish Dermatologic Development A/S believes that no significant differences exist. The Ellipse I²PL system should not raise new issues of safety and effectiveness and is judged to be 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

FEB 2 4 2005

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

Re: K043255
Trade/Device Name: Ellipse I^2 PL.
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: November 19, 2004
Received: November 26, 2004

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/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
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: K043255

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 (diffuse redness).

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	✓	✓	✓	✓	⊘	⊘
Note: Patients with darker Fitzpatrick Skin Types (4 or above) or who are suntanned should **always** be treated with extra care and attention. **Key: ✓ Allowed; ⊘ Not Allowed**							

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 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

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