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510(k) SUMMARY

Danish Dermatologic Development A/S (DDD) Ellipse Flex PPT 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: 08 November 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 Flex PPT.

Device Model number: 9ESF7255.

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)).
StarLuxTM Pulsed Light System (K041086) 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)).
Lumenis Family of IPL (K030342) 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)).

B. Description of Ellipse Flex PPT:

Ellipse Flex PPT 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.

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 Flex PPT:

Ellipse Flex PPT is intended for use in dermatology:

- Hair removal (permanent hair reduction).
- Treatment of benign pigmented lesions (including, but not limited to solar lentigines, ephelides, 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 Flex PPT* 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	Vessel size/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 Flex PPT to predicate devices:

	Ellipse Flex PPT	Ellipse I²PL	StarLuxTM Pulsed Light System	Lumenis Family of IPL
510(k) reference	Current submission	K043255	K041086	K030342
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 and Nd:YAG laser handle Lux 1064	Intense Pulsed Light (IPL)/broad spectrum light and Nd:YAG laser handle.
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 and for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae.	Surgical, aesthetic and cosmetic applications requiring selective photothermolysis and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology.
Energy spectrum	400-950 nm	555-950 nm	400-1200 nm	515-1200 nm
Energy output/ setting	0-26 J/cm ²	0-26 J/cm ²	Max 50 J/ cm ²	10-60 J/ cm ²
Pulse duration	1,5-100 ms	5-55 ms	1-500 ms	3-100 ms
Applicator/hand- piece spot size	10 x 48 mm	10 x 48 mm	16 x 46 mm, 12 x 28 mm, 10 x 15 mm	9 x 9 mm, 8 x 15 mm, 15 x 35 mm
Charge time/ repetition rate	1.5-2.0 s	1.5-2.0 s	Up to 2 Hz.	1 s
Cooling method	Cooling handpiece by circulating water.	Cooling handpiece by circulating water.	Contact cooling technology.	Skin cooling components integrated in hand piece.
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

Conclusion:

All applications of the Ellipse I²PL (DDD) are included in the Ellipse Flex PPT. StarLux™ (Palomar Medical Technologies, Inc.) has a broader range of applications than Ellipse Flex PPT, the intended use for Ellipse Flex PPT is covered by the StarLux™. Lumenis One of the *Lumenis Family of IPL* (Lumenis, Inc.) has a broader range of applications than Ellipse Flex PPT as Lumenis One includes a Laser module for vascular treatment applications in addition to the IPL modules. Ellipse Flex PPT does not employ a Laser module, only IPL. Ellipse Flex PPT thus utilizes a subset of the Lumenis One technologies.

The Ellipse Flex PPT has been evaluated and compared to the above systems and to their application modules (to Ellipse I²PL (DDD), Lumenis One (Lumenis, Inc.), and StarLux™ (Palomar Medical Technologies, Inc.)). The Ellipse Flex PPT system, as far as the identical modules, applications and intended uses are concerned, are judged to be identical to Ellipse I²PL and substantially equivalent to the Lumenis One (Lumenis, Inc.), and StarLux™ (Palomar Medical Technologies, Inc.) (predicate devices cleared in K043255, K041086 and, K030342 respectively)

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 Flex PPT system should not raise new issues of safety and effectiveness and is judged to be substantially equivalent to the mentioned predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ole Kofod
QA/RA Manager
Danish Dermatologic Development A/S
Agern Alle 11
DK-2970 Horsholm
Denmark

Re: K052688

Trade/Device Name: Ellipse Flex PPT, Model 9ESF7255
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 5, 2005
Received: November 9, 2005

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 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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

Enclosure

Abbreviated - 510(k) Notification - Corr. 1

Device Name: Ellipse Flex PPT

Indications for Use:

The Intended Use for Ellipse Flex PPT is:

Ellipse Flex PPT is intended for use in dermatology:

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- Treatment of inflammatory acne.

The Indications for Use for *Ellipse Flex PPT* are:

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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

Ole Kofod
(Signature)

Ole Kofod
(Typed Name)

4-11-2005
(Date)

K052688
(Premarket Notification 510(k) Number)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

Barbara Buehler for MCM
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052688