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
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 IPL (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)).
StarLux™ 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:

<table>
<thead>
<tr>
<th>Application</th>
<th>Treatment Variable</th>
<th>Fitzpatrick Skin Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair Removal</td>
<td></td>
<td>1 2 3 4 5 6</td>
</tr>
<tr>
<td>HR Applicator</td>
<td>Hair (Thin, Normal, Thick)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>HR-S Applicator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hair Removal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR-D Applicator</td>
<td>Hair (Thin, Normal, Thick)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Treatment of Benign Pigmented Lesions and Benign Vascular Lesions</td>
<td>Vessel size/Pigmentation</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Treatment of Telangiectasias</td>
<td>Vessel size (Thin, medium, thick)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Treatment of Port Wine Stains</td>
<td>Color (Red, blue)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Treatment of Individual Pigmented Lesions</td>
<td>Pigment Color</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Treatment of Inflammatory Acne</td>
<td></td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
</tbody>
</table>

Key: ✓ Allowed; ◦ Not Allowed
D. Comparison of Ellipse Flex PPT to predicate devices:

<table>
<thead>
<tr>
<th>510(k) reference</th>
<th>Ellipse Flex PPT</th>
<th>Ellipse IPL</th>
<th>StarLux™ Pulsed Light System</th>
<th>Lumenis Family of IPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current submission</td>
<td>Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.</td>
<td>Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.</td>
<td>Intense Pulsed Light (IPL)/broad spectrum light and Nd:YAG laser handle Lux 1064</td>
<td>Surgical, aesthetic and cosmetic applications requiring selective photothermolysis and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology.</td>
</tr>
</tbody>
</table>

- **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.

<table>
<thead>
<tr>
<th>Energy spectrum</th>
<th>400-950 nm</th>
<th>555-950 nm</th>
<th>400-1200 nm</th>
<th>515-1200 nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy output/setting</td>
<td>0-26 J/cm²</td>
<td>0-26 J/cm²</td>
<td>Max 50 J/cm²</td>
<td>10-60 J/cm²</td>
</tr>
<tr>
<td>Pulse duration</td>
<td>1.5-100 ms</td>
<td>5-55 ms</td>
<td>1-500 ms</td>
<td>3-100 ms</td>
</tr>
<tr>
<td>Applicator/hand-piece spot size</td>
<td>10 x 48 mm</td>
<td>10 x 48 mm</td>
<td>16 x 46 mm, 12 x 28 mm, 10 x 15 mm</td>
<td>9 x 9 mm, 8 x 15 mm, 15 x 35 mm</td>
</tr>
<tr>
<td>Charge time/repetition rate</td>
<td>1.5-2.0 s</td>
<td>1.5-2.0 s</td>
<td>Up to 2 Hz.</td>
<td>1 s</td>
</tr>
<tr>
<td>Cooling method</td>
<td>Cooling handpiece by circulating water.</td>
<td>Cooling handpiece by circulating water.</td>
<td>Contact cooling technology.</td>
<td>Skin cooling components integrated in hand piece.</td>
</tr>
<tr>
<td>Device classification</td>
<td>II; 21 CFR 878.4810, GEX</td>
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Conclusion:
All applications of the Ellipse 12PL (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 (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 12PL (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 12PL 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.
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" (21 CFR 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,

[Signature]

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

Enclosure
Device Name: Ellipse Flex PPT

Indications for Use:

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

510(k) Number K052688