K 041969

OCT 1 9 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SYNERON MEDICAL Ltd. Aurora DS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Syneron Medical Ltd., Sultam Industrial park, P.O.B. 550, Yokneam Elite 20692, Israel.
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Name of the Device: Aurora DS

Predicate Devices: The Aurora DS is substantially equivalent to a combination of 3 light powered surgical instruments (21 CFR 878.4810, procode GEX): Aurora DS, manufactured by Syneron Medical Ltd. and subject of K033586. Palomar StarLux, manufactured by Palomar medical products inc. and subject of K033549. Lovely system, manufactured by Msq Ltd. and subject of K033946

Device Description: The Aurora DS is a device indicated for the removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction. The Aurora DS treatment is based on the principle of *selective (electromagnetic) thermolysis*. According to this principle, parameters of optical and RF energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively damage to the hair follicle without damaging the surrounding tissues.

The Aurora DS is indicated for the removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction.

Based upon an analysis of the overall performance characteristic for the device, Syneron Medical Ltd. believes that no significant differences present. Therefore the Aurora DS should raise no new issues of safety or effectiveness.

21/7/04

Date

Dr. Amir Waldman,
Director regulatory affairs
Syneron medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2004

Dr. Amir Waldman
Director Regulatory Affairs
Syneron Medical Ltd.
P.O Box 550
Sultam Industrial Park
Yokneam Elite, Israel 20692

Re: K041969
Trade/Device Name: Aurora DS
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, GEI
Dated: July 19, 2004
Received: July 22, 2004

Dear Dr.Waldman:

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,

for Miriam C. Provost

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

510(k) Number (if known) K041969

Device Name **Aurora DS .**

Indications For Use:

The Aurora DS is indicated for the removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K041969