K073715

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 23 2008

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., Industrial Park, P.O.B. 550

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Name of the Device: LipoLite (eLipo)

Predicate Devices: This is a 510(k) submission for the LipoLite (eLipo) device that is substantially equivalent to the following cleared device: Cynosure SmartLipo Laser (Cynosure Inc., K062321).

Device Description: The LipoLite (eLipo) is a microprocessor-controlled 1064 nm Nd:YAG laser system. It is composed of the following main units: high voltage power supply, laser assembly, control panel and cooling unit. The LipoLite (eLipo) delivers pulsed energy to pre-determined anatomical areas via an optical fiber.

Indications for Use: The LipoLite (eLipo) is intended for dermatological procedures requiring incision, excision, vaporization, ablation and coagulation of soft tissue. The LipoLite (eLipo) is further indicated for laser-assisted lipolysis.

Conclusion: The overall specifications, principle of operation, performance characteristics and indications for use of the LipoLite (eLipo) device are substantially equivalent to those of the predicate device. Therefore, the LipoLite (eLipo) device should raise no new issues of safety and effectiveness and is safe and effective for the indicated uses.

April 10, 2008
Date

Yoni Iger, Ph.D.
Director of Clinical & Regulatory Affairs
Syneron Medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Syneron Medical Ltd.
% Yoni Iger
Industrial Zone, P.O. Box 550
Yokneam Illit
20692, Israel

APR 23 2008

Re: K073715
Trade/Device Name: LipoLite (eLipo)
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: April 12, 2008
Received: April 17, 2008

Dear Yoni Iger:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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 (if known): K073715

Device Name: LipoLite (eLipo)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Ogden for nxn

(Division Sign-Off)
Division of General, Restorative, Page 1 of 1
and Neurological Devices

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