K050397 JUN 9 - 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SYNERON MEDICAL Ltd. VELASMOOTH, SHAPER

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

Submitter: Syneron Medical Ltd., Sultam Industrial park, P.O.R.550, Yokneam Elite 20692, Israel.

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Name of the Device: Vela smooth, Shaper

Predicate Devices: Vela smooth, Shaper is substantially equivalent to a combination of the following devices: LPG therapeutic massager, manufactured by LPG systems and subject of K990445. WS-501 Heat lamp, manufactured by Lhasa Medical Inc. and subject of K013197. TDP CQ-27 heat lamp, manufactured by Lhasa Medical, Inc. and subject of K003538. Aurora DS, manufactured by Syneron medical Ltd. and subject of K031988. ThermaCool TC, manufactured by Thermage Inc. and subject of K030142.

Device Description: The Vela smooth, Shaper treatment is based on the simultaneous application of heat to the tissue with light energy at a controlled Infrared wavelength, conducted RF energy, and mechanical manipulations of the skin.

The Vela smooth, Shaper is indicated for the relief of minor muscle aches and pain. Relieve of muscle spasm. Temporary improvement of local blood circulation. Temporary reduction in the appearance of cellulite.

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

February 13, 2005

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

JUN 9 - 2005

Syneron Medical, LTD.
C/o Mr. Donald E. Segal
Alston & Bird, LLP
601 Pennsylvania Avenue, N.W.
North Building, 10th floor
Washington, District of Columbia 20004

Re: K050397
Trade/Device Name: Vela smooth, Shaper
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: NUV
Dated: May 23,2005
Received: May 23,2005

Dear Mr. Segal:

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 iinnual 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,

Miriam C. Provost, Ph.D.
Acting 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): K050397

Device Name: Vela smooth, Shaper.

Indications For Use: The Vela smooth, Shaper is indicated for the relief of minor muscle aches and pain. Relief of muscle spasm Temporary improvement of local blood circulation. Temporary reduction in the appearance of cellulite.

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

510(k) Number K050397