

K071872

AUG 22 2007

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

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,
Yokneam Illit, 20692, Israel.
Tel. +972-73-244-2200 ext. 591, Fax +972-73-244-2202

Name of the Device: VelaShape

Predicate Devices: This is special 510k for the VelaShape (name change from VelaSmooth, Shaper) that is substantially equivalent to the following cleared device: VelaSmooth, Shaper, manufactured by Syneron Medical Ltd. and subject of K050397 and of K070092.

Device Description: The VelaShape treatment is based on the simultaneous application of heat and mechanical manipulation to the tissue, wherein the heat is derived from light energy at a controlled infrared wavelength and from conducted RF energy, and the mechanical manipulation is derived from massage and/or vacuum.

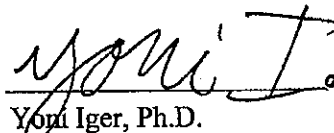
The VelaShape is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite (K050397). The VelaShape is also indicated for temporary reduction of thighs circumferences (K070092).

The modification of the increased RF power of the VelaShape does not affect the intended use or alter the fundamental scientific technology background of the device, nor that it affect the mode of use. There are no labeling changes that affect the intended use of the device.

The modification of the increased RF power raises no new issues of safety or effectiveness.

August 16, 2007

Date



Yoni Iger, Ph.D.

Director of Clinical & Regulatory Affairs
Syneron Medical Ltd.



Food and Drug Administration
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AUG 22 2007

Re: K071872

Trade/Device Name: VelaShape

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: July 4, 2007

Received: July 6, 2007

Dear Dr. 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

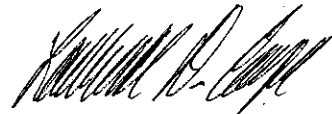
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quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



FOR

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): K071872

Device Name: VelaShape

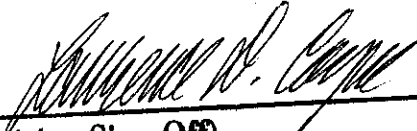
Indications for Use:

The VelaShape 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, and for temporary reduction of thighs circumferences.

Prescription Use 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
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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