K122579 1/2

510(k) SUMMARY
Syneron Medical Ltd's VelaShape System

SEP 13 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: August 22, 2012

Name of Device

VelaShape

Common or Usual Name

Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name

NUV- Laser surgical instrument for use in general and plastic surgery and in dermatology

Predicate Devices

This Special 510(k) for the modified VelaShape is substantially equivalent to the previously cleared VelaShape device (K071872) manufactured by Syneron Medical, Ltd.

Intended Use / 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.

Technological Characteristics

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 radio frequency (RF) energy and the mechanical manipulation is derived from massage and/or vacuum.

Performance Data

Minor hardware modifications were performed to support the change of the VelaShape system infrared (IR) light source. Verification testing was performed to evaluate this modification to ensure the performance of the new light source is compatible with the previously cleared specifications. Electromagnetic compatibility or electrical safety testing was not required to support this modification. Performance testing demonstrates that the VelaShape system performs according to specifications and functions as intended.

Substantial Equivalence

The change of the IR light source from a tungsten halogen lamp to a light-emitting diode (LED) for the VelaShape does not affect the indications for use or alter the fundamental scientific technology background of the device, nor does it affect the mode of use. There are no labeling changes that affect the indications for use of the device. The modification of the IR light source to LED raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Syneron Medical, Limited
% Mr. Sam Wade
Global Vice President, Regulatory Affairs
Industrial Zone Tavor Building P.O.B. 550
Yokneam, Illit Israel 20692

Re: K122579
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: Class II
Product Code: MUV
Dated: August 22, 2012
Received: August 30, 2012

Dear Mr. Wade:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122579

Device Name: VelaShape

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)

Neil R Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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