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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR - 2 2010

GENERAL INFORMATION

Trade Name	SMOOTHSHAPES® XV SYSTEM
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	NUV
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	Elemé SmoothShapes (K083629) Syneron Velashape (K071872)
Submitter	Elemé Medical, Inc. Heron Cove Office Park 10 Al Paul Lane, Suite 102 Merrimack, NH 03054 USA
Contacts	William H. McGrail Vice President, Research & Development, Clinical & Regulatory bmcgrail@elememedical.com Phone:603-816-1603 Fax: 603-882-4762

DEVICE DESCRIPTION

The SMOOTHSHAPES® XV System featuring Photomology® technology is designed to temporarily reduce the appearance of cellulite. The proprietary Photomology technology combines heating through dynamic energy (laser and light) with mechanical manipulation (contoured rollers and vacuum) to temporarily reduce the appearance of cellulite.

Photomology is based on the transcutaneous application of a dynamic combination of dual-band laser/light. The Photomology Module combines 650 nm light from LEDs and 915 nm light from laser diodes with mechanical massage (rollers) and vacuum (suction).

INTENDED USE

The Elemé Medical SMOOTHSHAPES® XV system is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

SUBSTANTIAL EQUIVALENCE

The SMOOTHSHAPES® XV System is substantially equivalent in its use and performance to the predicate devices with respect to technological features and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 2 2010

Elemé Medical, Inc.
% Mr. William H. McGrail
VP, Research & Development,
Clinical & Regulatory
10 Al Paul Lane, Suite 102
Merrimack, New Hampshire 03054

Re: K100230
Trade/Device Name: SmoothShapes® XV System
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: NUV
Dated: March 08, 2010
Received: March 09, 2010

Dear Mr. McGrail:

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 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

510(k) Number (if known): K100230

Device Name: SMOOTHSHAPES® **XV System**

Indications for Use:

The Elemé Medical SMOOTHSHAPES® XV system is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

Prescription Use ✓ (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)

for mxm

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

510(k) Number K100230