DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 7, 2016

Syneron Medical Ltd.
% Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K161952
Trade/Device Name: UltraShape System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System for Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: October 3, 2016
Received: October 3, 2016

Dear Ms. Hogan:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
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Center for Devices and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K161952

Device Name

UltraShape System

Indications for Use *(Describe)*

The UltraShape System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) for lipolysis (breakdown of fat) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference and for use on the flanks.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

Syneron Medical Ltd.'s UltraShape System

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Date Prepared: November 3, 2016

Name of Device

Syneron UltraShape System

Common or Usual Name

Focused Ultrasound Stimulator System for Aesthetic Use

Classification

Focused Ultrasound Stimulator System for Aesthetic Use

21 CFR 878.4590, Class II, product code OHV

Predicate Device

Syneron UltraShape (K141708)

Intended Use / Indications for Use

The UltraShape System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) for lipolysis (breakdown of fat) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference and for use on the flanks.

Device Description

The UltraShape System is comprised of multiple components, including the control unit and two ultrasonic transducers. The UltraShape System selectively targets subcutaneous adipose tissue via focused ultrasound for the purpose of non-invasive aesthetic body contouring. The transducers are electro-mechanical devices that convert an electrical signal into mechanical (acoustical) energy. The operating parameters of the UltraShape System achieve selective disruption of adipose tissue without damaging neighboring tissues such as blood vessels, nerves, or muscle. The UltraShape System has two treatment modes available, the Single Focus Deep Mode and the Super Mode.

Technological Characteristics

The UltraShape System has very similar technological characteristics compared to its predicate. The UltraShape and the predicate are both comprised of the system console, including the computer, and two ultrasonic transducers. The transducers deliver the focused ultrasound energy beam to the targeted treatment area, and real-time optical and acoustic feedback (optional) on the treatment is provided via the tracking and guidance system. With both the UltraShape and its predicate, the transducers' functionality is based on the piezoelectric effect implemented with the ceramic element.

In addition, the UltraShape System has the same treatment parameters as the previously cleared UltraShape device, including the same frequency, burst duration, node duration, and user interface. In addition, the power intensity levels were previously cleared for the UltraShape. The focal distribution of the energy beams delivered to the treatment area is consistent between the UltraShape and its predicate, including the focal depth, diameter, and length. Software changes were also made to the updated version of the UltraShape. Notably, the UltraShape System has been evaluated in clinical, in vivo, and bench testing, and none of the changes raise new types of safety or effectiveness questions compared to the predicate.

Therefore, the UltraShape System has similar technological characteristics compared to its predicate.

Performance Data

Nonclinical Performance Testing. The following nonclinical performance testing was previously conducted to support the substantial equivalence of the UltraShape System to the predicate device, consistent with FDA's "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use" (2011). In all instances, the UltraShape System functioned as intended.

- Biocompatibility testing in accordance with ISO 10993 for skin irritation, sensitization, cytotoxicity testing supported the biocompatibility of the patient-contacting components of the device.

- Beam profile testing demonstrated that the acoustic energy is delivered and concentrated in the desired target location.

- Acoustic power testing demonstrated that the acoustic power of the transducers is highly predictable with low variability.

- In vitro acoustic and thermal measurements demonstrated the safety of non-targeted tissues both proximal and distal to the targeted region.

- Software verification and validation was performed, and demonstrated that the software performs as intended.

- Electrical safety (IEC 60601-1), electromagnetic compatibility (IEC 60601-1-2) and electromagnetic immunity testing was conducted and results were passing.

- In vivo testing in an animal model was performed which demonstrated the treatment effects of the UltraShape, and supported its safety and efficacy profile for the intended use.

Clinical Data: In addition, clinical evaluation of the device in the intended population was performed in several separate prospective studies, including a single-arm, prospective, self-controlled study to evaluate the safety and effectiveness of the UltraShape device for non-invasive lipolysis of the flanks. A total of 48 subjects were enrolled and treated in the study (of which 46 subjects completed the study) at 3 U.S. sites. The study included females (83%) and males (17%) across a range of ages, races, ethnicities, and skin types. The mean age was 45 years and the majority of the subjects were Caucasian. The baseline mean weight was 68±9 kg and mean BMI was 25.28±2.08 kg/m^2.

Each subject received 3 biweekly treatments on one randomized flank, while the other flank remained un-treated throughout the study. Subject follow up was conducted at 4 weeks, 8 weeks, and 16 weeks after the last treatment. The study included visual assessment of the flanks by 2 blinded reviewers as well as fat thickness measurements of the post treatment flanks compared to baseline measurements.

Study results demonstrated that the UltraShape treatment at the flanks was accompanied with no or minimal discomfort, consistent with results observed for the prior UltraShape clearances. Throughout the study, no adverse events were reported, and the anticipated immediate responses after treatment (e.g., mild erythema, mild edema) were consistent with those observed with other similar devices, such as the previously cleared UltraShape systems (K133238, K160896) and Cynosure's SculpSure (K150230). The responses were mild and resolved completely within days without any intervention.

The primary endpoint was met, where 80% of treated versus control flanks and pre versus post treatment photographs were correctly identified by blinded reviewers. One subject was not included in the primary endpoint blinded review assessment because of the poor quality of the post-treatment photograph for this subject. Although results for this subject showed fat reduction at the treated flank by caliper (-1.0 mm (2.38%)) and by ultrasound (-0.55 mm (-2.40%)), if this subject was imputed as a failure in a sensitivity analysis of the primary endpoint, the study success rate would be 78%, which would not meet the primary endpoint threshold of 80%.

In addition, secondary effectiveness endpoints demonstrated that fat thickness reduction on the treated flank was statistically significantly greater compared to the control flank at each

follow up visit as measured by ultrasound. Fat thickness reduction results following UltraShape treatment were greater compared to controls as measured by caliper (reaching statistical significance in absolute fat thickness reduction at 16 week follow up). At 4 week follow up, investigator satisfaction measured 70%, and subsequent results reflected lower satisfaction with increasing time from treatment (53% at 8 weeks follow up, 43% at 16 weeks follow up). In terms of subject satisfaction, at 4, 8 and 16 weeks following end of treatments, 43%, 47%, and 41% subjects were satisfied or very satisfied. The study design and results are further summarized in the table below.

Study Design	Prospective, single-arm, self-controlled, multicenter clinical study
Sample size	48 subjects at 3 sites were enrolled and treated in the study
Principal Eligibility Criteria	• Fat thickness of at least 1.5 cm in the treated area as measured by calibrated caliper. • BMI interval: 22 ≤ BMI ≤ 30 (normal to overweight, but not obese). • General good health confirmed by medical history and skin examination of the treated area.
Follow up intervals	3 treatment visits and follow up visits at 4 weeks, 8 weeks, and 16 weeks.
Endpoints	**Primary**: Fat reduction in flanks was evaluated by visual assessment of randomized photographs of before (baseline) versus after (16 weeks following last treatment), as well as treated versus control flanks, by 2 blinded reviewers. The primary endpoint was achieved when at least 80% of treated versus control flanks and pre- versus post-treatment photographs were correctly identified. **Secondary**: - Fat thickness reduction on the treated flank compared to the control flank, measured by ultrasound. - Fat thickness reduction on the treated flank compared to the control flank, measured by caliper. - Investigator satisfaction assessment. - Subject satisfaction self-assessment. - Subjects' comfort level assessed immediately after each treatment.
Effectiveness Results	**Primary**: Met endpoint; blinded reviewers identified correctly (by agreement between the blinded reviewers) both the pre-/post-treatment photographs as well as the treated/un-treated flanks in 80% (36 of 45) subjects. **Secondary**: - Fat thickness reduction results following UltraShape treatment were statistically significantly greater compared to controls as measured by ultrasound. - Fat thickness reduction results following UltraShape treatment were greater compared to controls as measured by caliper (reaching statistical significance in absolute fat thickness reduction at 16 week follow up). - Investigators were satisfied with results following UltraShape treatment for 70% of the subjects at 4 week follow up, 53% of the subjects at 8 week follow up, and 43% of the subjects at 16 week follow up. - At 4, 8 and 16 weeks following end of treatments, 43%, 47%, and 41% of the subjects were satisfied or very satisfied. - Subjects reported no to minimal pain for each of the three treatments.
Safety Results	No adverse events were reported after 141 treatment sessions were conducted. The only immediate responses recorded were mild and resolved completely

	within days without any intervention.

Therefore, clinical evaluation of the UltraShape device demonstrated the favorable performance and safety profile of the device for lipolysis of the flanks. Results thus further support substantial equivalence of the device compared to the predicate.

Substantial Equivalence

The UltraShape has the same intended use and similar indications for use, technological characteristics and principles of operation as its predicate device. The technological differences between the UltraShape and its predicate mainly consist of minor improvements to the device to facilitate use. Nonclinical and clinical studies of the UltraShape have demonstrated the safety and effectiveness profile of the UltraShape in the intended population. Thus, the UltraShape is substantially equivalent to the predicate device.

Conclusion

Syneron's UltraShape System is a Focused Ultrasound Stimulator System for Aesthetic Use Class II device that has been evaluated in nonclinical and clinical testing in accordance with FDA's Special Controls Guidance Document. Testing demonstrated that the device performs as intended. The UltraShape device is substantially equivalent to its predicate device (K141708).