DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 15, 2017

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

Re: K170370
Trade/Device Name: UltraShape Power System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System for Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: April 12, 2017
Received: April 12, 2017

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 -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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)*

K170370

Device Name

UltraShape Power System

Indications for Use *(Describe)*

The UltraShape Power 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 fat reduction in the flanks and thighs.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Syneron Medical Ltd.'s UltraShape Power System

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

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Date Prepared: February 6, 2017

Name of Device

Syneron UltraShape Power System

Common or Usual Name

Focused Ultrasound Stimulator System for Aesthetic Use

Classification

21 CFR 878.4590, Class II, product code OHV

Predicate Devices

Syneron UltraShape System (K162163, K161952) (Primary Predicate)

Syneron UltraShape Power System (K160896)

Intended Use / Indications for Use

The UltraShape Power 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 fat reduction in the flanks and thighs.

Device Description

The UltraShape Power System is comprised of multiple components, including the control unit and an ultrasonic transducer. The UltraShape Power System selectively targets subcutaneous adipose tissue via focused ultrasound for the purpose of non-invasive aesthetic body contouring. The transducer is an electro-mechanical device that converts an electrical signal into mechanical (acoustical) energy. The operating parameters of the UltraShape Power System achieve selective disruption of adipose tissue without damaging neighboring tissues such as blood vessels, nerves, or muscle.

Technological Characteristics

The UltraShape Power System has similar technological characteristics as its predicate. Both devices are comprised of the system console, including the computer and a small (U-Sculpt Power)

transducer. The transducer delivers 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 Power System and its predicate, the transducer's functionality is based on the piezoelectric effect implemented with the ceramic element.

In addition, the subject UltraShape Power System has the same treatment parameters as the previously cleared UltraShape Power device, including the same frequency, burst duration, node duration, and user interface. The power intensity levels were previously cleared for the UltraShape Power device, and the focal distribution of the energy beams delivered to the treatment area is consistent between the device and its predicate, including the focal depth, diameter, and length.

Therefore, the subject UltraShape Power System has very similar technological characteristics as its predicate.

Performance Data

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

- Beam profile testing demonstrated that the acoustic energy is delivered and concentrated in the desired target location, at a focal depth similar to that of the predicate devices.
- Acoustic power testing demonstrated that the acoustic power of the transducer met specifications, is well defined, and presents low variability.
- In vitro thermal evaluation was conducted and results were passing, demonstrating the absence of thermal coagulation or lesion in tissue.
- Software verification and validation was performed, and demonstrated that the software performs as intended.
- Electrical safety (IEC 60601-1, IEC 60601-2-37) and electromagnetic compatibility (IEC 60601-1-2) testing was conducted and results were passing.
- Biocompatibility of the patient-contacting components of the device was established.
- In vivo testing in an animal model was performed to evaluate the device treatment mode, and results supported the device safety and efficacy profile for the intended use.

In addition, clinical evaluation of the UltraShape System (cleared in K161952) 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 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. 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 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.

Study Design	Prospective, single-arm, self-controlled, multicenter clinical study
	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.

In addition, clinical evaluation of the UltraShape System (cleared in K162163) in the intended population for the non-invasive lipolysis of the thighs was also performed in a prospective, single-arm, self-controlled study. A total of 47 subjects (all female) across a range of ages, ethnicities, and skin types were enrolled at 3 U.S. sites. The mean age was 46 years and the majority of the subjects were Caucasian. The mean weight at baseline was 70±10 kg (range 51-103 kg). Each subject received 3 biweekly treatments on one randomized thigh, while the other thigh remained un-treated throughout the study to serve as a control. Subject follow up was conducted at 4 weeks, 8 weeks, and 16 weeks after the last treatment.

The study met its primary effectiveness endpoint, where blinded reviewers who were shown randomized pairs of thigh photographs correctly identified both pre- versus post-treatment and treated versus untreated thighs in 81% of cases. Further, even in the Intent-to-Treat population, with worst case imputation where all missing data were treated as failures, 64% of the subjects were successes. UltraShape treated thighs showed statistically significantly greater circumference reduction compared to the control thighs at each follow-up visit. Fat thickness reduction results following UltraShape treatment were statistically significantly greater compared to controls as measured by ultrasound. Investigators were satisfied with results following UltraShape treatment for 77% of the subjects at 4 week follow up, 81% of the subjects at 8 week follow up, and 68% of the subjects at 16 week follow up. At 4, 8 and 16 weeks following end of treatments, 62%, 61% and 68% of the subjects were satisfied or very satisfied. Finally, treatment with the UltraShape System in the thigh area demonstrated a strong positive safety profile, with no adverse events reported after 128 treatment sessions and only mild anticipated treatment responses (*e.g.*, erythema) that resolved without intervention. This is consistent with the results observed for prior UltraShape clearances, including the predicate device.

The study design and results are further summarized in the table below.

Study Design	Prospective, single-arm, self-controlled, multicenter clinical study
Sample size	47 subjects at 3 sites were enrolled 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 at least 1.5 cm in the treated area as measured). • General good health confirmed by medical history and skin examination of the treated area.
Follow up Intervals Endpoints	3 treatment visits and follow up visits at 4 weeks, 8 weeks, and 16 weeks. **Primary**: Circumference and fat reduction in thighs was based on visual assessment of randomized photographs of before (baseline) versus after (16 weeks following last treatment), as well as treated versus untreated thighs by 2 blinded reviewers. The primary endpoint was achieved when at least 80% of treated versus control thighs and pre- versus post-treatment photographs were correctly identified. **Secondary**: - Circumference reduction on treated thigh compared to control thigh. - Fat thickness reduction on the treated thigh compared to the control thigh, measured by ultrasound. - Fat thickness reduction on the treated thigh compared to the control thigh, 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 thighs in 81% (30 of 37) subjects. **Secondary**: - UltraShape treated thighs showed statistically significantly greater circumference reduction compared to the control thighs at each follow up visit. - 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, although the difference was not statistically significant at all visits. - Investigators were satisfied with results following UltraShape treatment for 77% of the subjects at 4 week follow up, 81% of the subjects at 8 week follow up, and 68% of the subjects at 16 week follow up. - At 4, 8 and 16 weeks following end of treatments, 62%, 61% and 68% of the subjects were satisfied or very satisfied. - Subjects reported no to minimal pain on average for each of the three treatments.
Safety Results	No adverse events were reported after 128 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 design demonstrated its favorable performance and safety profile for lipolysis of the flanks and thighs. Results thus further support substantial equivalence of the device as compared to the predicate.

Substantial Equivalence

The UltraShape Power has the same intended use and very similar indications for use, technological characteristics, and principles of operation as its predicate devices. The added indications for use in the thighs and flanks are supported by the clinical data. The technological differences between the UltraShape Power and its prior clearance mainly consist of minor improvements to the device to facilitate use and customer preference. Nonclinical and clinical studies of the device have demonstrated that the minor differences do not raise new types of safety or effectiveness questions. Thus, the UltraShape Power is substantially equivalent to the predicate devices.

Conclusion

Syneron's UltraShape Power 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 Power device is substantially equivalent to its predicate devices.