DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 8, 2016

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

Re: K160896
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: June 6, 2016
Received: June 6, 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 yours,

Jennifer R. Stevenson -A

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 below.

510(k) Number *(if known)*
K160896

Device Name
UltraShape Power System

Indications for Use *(Describe)*
The UltraShape Power System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference.

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

Syneron Medical Ltd.
P.O.B. 550 Industrial Zone Tavor Building
Yokneam Illit, 20692 Israel

Phone: 972-73-244-2200
Facsimile: 972-73-244-2202

Company Contact Person: Ruthie Amir, MD, Global Vice President of Clinical, Regulatory and Education

Submission Contact Person: Janice Hogan, Hogan Lovells US LLP

Date Prepared: July 7, 2016

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 Medical Ltd.'s UltraShape (K141708)
Syneron Medical Ltd.'s Contour I V3.1 (K133238)

Intended Use / Indications for Use

The UltraShape Power System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference.

Device Description

The UltraShape Power System is comprised of multiple components, including the control unit and two ultrasonic transducers. The UltraShape Power 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 Power System achieve selective disruption of adipose tissue without damaging neighboring tissues such as blood vessels, nerves, or muscle.

The primary purpose of this submission is to add an increased acoustic intensity level to the device. Additional minor changes since the prior clearances were also included as part of this submission.

Technological Characteristics

The UltraShape Power System has very similar technological characteristics compared to its predicates. The device continues to be a focused ultrasound device intended for the same indications as the predicates. The proposed and predicate devices are all prescription use only devices and all require the same number of treatments per treatment session. The targeted anatomic area for the UltraShape Power System is identical to the predicate devices. Each of the device systems is comprised of the system control unit, including the computer, and ultrasonic transducer(s). The transducer is the patient-contacting component for both the proposed and predicates devices. The transducers for the UltraShape Power System and the predicates are electromechanical devices that convert the electrical signal into mechanical (acoustic) energy using the same piezoelectric ceramic acoustics core. The UltraShape Power System and the predicates all have a real-time video tracking and guidance system that guides the operator through treatment, and captures and processes the treatment information. The screen size for the real-time display is the same for the proposed and predicate devices. The UltraShape Power System and its predicates all include the same temperature sensors as a safety feature.

In addition, the UltraShape Power System has the same frequency, burst duration, node duration, and user interface as the predicates. The UltraShape Power and its predicates deliver ultrasound energy to the treatment area in a similar manner with similar focal distribution. The primary difference between the UltraShape Power and its predicates is the additional option for treatment at an increased acoustic intensity using the small transducer; the subject UltraShape small transducer includes acoustic intensity level of 660 W/cm^2, compared to the predicate small transducer's acoustic intensity level of 550 W/cm^2.

Further, the UltraShape Power System also includes minor modifications to the pulser and power distribution unit compared to the predicates. The Pulser component of the device was modified to be smaller with a new design, and this change did not require any changes in the treatment parameters. An additional treatment mode option was also added. Minor improvements were also made to the UltraShape Power System compared to the predicates, including improved accuracy for output power and temperature measurement and an improved video camera (HD digital instead of analog). None of these changes significantly impact device performance or raise new types of safety and effectiveness questions.

The technological differences between the UltraShape Power and its predicates have been evaluated in clinical testing, and results demonstrated that the device performs in a substantially equivalent manner with no adverse events. Therefore, the changes do not raise any new types of safety or effectiveness questions.

Performance Data

The following nonclinical performance testing was conducted to support the substantial equivalence of the UltraShape Power 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 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 transducers 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 device in the intended population was performed in a prospective single arm study. The study evaluated the safety and effectiveness of the UltraShape Power in 43 enrolled subjects. Eligible subjects received treatments with continued follow up to 12 weeks after treatment. Mean age was 48 years and most of the subjects were females (95%). All subjects were Caucasian. The study primary efficacy endpoint was achieved with statistically significant reduction in abdominal circumference, progressing from 2 weeks following the first treatment to 12 weeks post treatment (2.55 cm reduction). The circumference reduction was consistent at all measurements (midline, 2 cm above midline and 2 cm below midline). Responder analysis results also demonstrated that the majority of subjects achieved circumference reduction with device treatment. The study data also demonstrated statistically significant fat thickness reduction compared to baseline, reaching 3.63 mm reduction at 12 weeks post treatment (mean change adjusted for baseline 3.77±1.11 mm). Subjects were asked to rate their overall satisfaction with treatment on a 5-point scale (-2=very disappointed to +2=very satisfied). By 2 weeks after treatment, approximately two-thirds of subjects were satisfied (somewhat satisfied or very satisfied), which continued at 4 weeks follow up; subsequent results reflected slightly lower satisfaction with increasing time from treatment. At 2 week follow-up, 81% of subjects stated that they would recommend the procedure to a friend or family, again with slightly decreasing rates with increasing time from treatment. Approximately half of the subjects were satisfied with the time required for the treatment results at 2 weeks, slightly decreasing over subsequent

follow-up visits, and approximately one-third of subjects felt slimmer after treatment (30%), with similar results at subsequent follow-up visits. Regarding the comfort of the treatment, 100% of subjects felt it was comfortable at all time points, with the exception of a single subject at 8 and 10 weeks (96% of subjects felt comfortable). Overall, subjects reported that they experienced improvement following treatment with the UltraShape Power. Treatment with the UltraShape Power demonstrated a positive safety profile, with no adverse events.

Additional safety data from a prospective clinical study of 21 patients (11 patients treated with added treatment mode) further confirm the safety profile of the device. Subjects underwent 3 treatment sessions each 2 weeks apart; follow-up visits occurred at 2, 4, 8 and 12 weeks after the last treatment visit. The study results further supported the safety profile of device treatment with only one minor event from which the patient completely recovered without the need for any intervention. Subjects reported minimal discomfort and overall satisfaction with the treatments.

Therefore, performance data demonstrated the safety and effectiveness profile of the UltraShape Power for its intended use.

Substantial Equivalence

The UltraShape Power has the same indications for use and similar technological characteristics and principles of operation as its predicate devices. The technological differences between the UltraShape Power and previously cleared UltraShape devices, including the increased acoustic intensity, additional treatment mode, and software/hardware changes, do not raise new types of safety or effectiveness questions. Nonclinical and clinical studies have been conducted to evaluate the UltraShape Power, and results confirm that the device performs as intended and in a similar manner compared to the predicates. 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 (K141708, K133238).