DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 20, 2017

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

Re: K163415
Trade/Device Name: SlimShape System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 30, 2017
Received: March 30, 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)*

K163415

Device Name

SlimShape System

Indications for Use *(Describe)*

The SlimShape System is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen.

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 SlimShape System

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Date Prepared: April 19, 2017

Name of Device

Syneron SlimShape System

Common or Usual Name

Electrosurgical, Cutting & Coagulation & Accessories

Classification

Electrosurgical, Cutting & Coagulation & Accessories

21 CFR 878.4400, Class II, product code GEI

Predicate Device

Syneron Medical Ltd.'s Transcend System (K120510)

Intended Use / Indications for Use

The SlimShape System is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen.

Device Description

The SlimShape System is comprised of a console and an applicator that delivers radiofrequency energy to the fat tissue and also applies mechanical vacuum to the treatment area. The SlimShape System is designed to enable hands-free abdominal treatment that is based on a predefined user protocol. The system also incorporates a skin temperature control mechanism as a safety feature during treatment. Users interface with and control the SlimShape System via the touch-screen panel.

Technological Characteristics

The SlimShape System has very similar technological characteristics compared to its predicate. The SlimShape and the predicate are both comprised of a system console and applicator(s). The console in both devices consists of the RF generator, vacuum pump, computer, and the touch-screen control panel. Although the SlimShape System does not include infrared light, this difference compared to the predicate does not alter the intended therapeutic effect of the device or raise new types of safety or effectiveness questions, as demonstrated in clinical and nonclinical performance testing. Further, technological differences in the shape and dimensions of the applicators of the SlimShape and predicate device also do not raise any different safety or effectiveness questions, given that the device applicators have the same or similar energy parameters with similar treatment areas. In addition, the applicators of both systems similarly apply the vacuum and RF energy to the treated area. Both devices use the 1 MHz bipolar sinusoidal RF signal. In addition, the power intensity level for SlimShape is within the maximum output power cleared for the predicate device. Both devices include a temperature control mechanism through temperature sensors in the applicator. Notably, the SlimShape System has been evaluated in clinical and bench testing, and the technological differences do not raise new types of safety or effectiveness questions compared to the predicate.

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

Performance Data

Nonclinical Performance Testing: The following nonclinical performance testing was conducted to support the substantial equivalence of the SlimShape System to the predicate device. In all instances, the SlimShape System functioned as intended.

- Biocompatibility of the patient-contacting components of the device was established. Cytotoxicity testing per ISO 10993-5, sensitization testing per ISO 10993-10, and irritation testing per ISO 10993-10 were performed to further confirm the biocompatibility of the device.

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

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

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 of the SlimShape device for non-invasive lipolysis and circumference reduction of the abdomen. The study enrolled 52 subjects who were treated with the SlimShape device. The study included Caucasian females (87%) and males (13%) across a range of ages and skin types. Mean age was 45 years. The baseline mean weight was 72±11 kg and mean BMI was 26.29±2.62 kg/m^2.

Forty subjects underwent 3 biweekly treatments using the Temperature Control mode on the abdomen. Subject follow up was conducted at 4 weeks, 8 weeks, and 12 weeks after the last treatment. The study included circumference and fat thickness measurements of the post treatment abdomen compared to baseline measurements, as well as visual assessment of the before and after photographs by 2 blinded reviewers.

The study met its primary efficacy endpoint, with an average of 1.98±2.53 cm reduction in abdominal circumference and an average of 6.03±3.09 mm reduction (-24.5%±11.3%) in fat thickness measured by ultrasound at 12 weeks follow-up compared to baseline.

Secondary effectiveness endpoints demonstrated that pre- and post-treatment photographs of the subjects were correctly identified in 86% of the photographs by blinded reviewers. Additional analysis demonstrated reductions in abdomen circumference and fat thickness over time and reductions in circumference at upper and lower abdomen. Responder analysis showed that 64% of the subjects at 12 week follow up achieved at least 1.5 cm of circumference reduction. In addition, 59% of subjects were very satisfied or satisfied with the treatments at 12 week follow up, and 77% of subjects would recommend the procedure. Furthermore, 91% of the subjects reported none to moderate pain.

Out of a total of 144 treatment sessions, 6 subjects reported on 8 mild adverse events. There were no reports of serious or unanticipated adverse events. No subjects discontinued from the study due to adverse events. The anticipated immediate responses after treatment (e.g., erythema, edema) were consistent with those observed with other similar devices. The immediate responses were transient and resolved completely within several hours without any intervention.

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

Study Design	Prospective, single-arm, self-controlled, single-site clinical study
Sample size	52 subjects at one site were enrolled and treated in the study
Principal Eligibility Criteria	• Healthy male or female, ≥ 18 and ≤ 65 years of age at the time of enrollment. • Subject agrees to maintain their weight by not making any major changes in their diet or lifestyle during the course of the study. • 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 12 weeks.

Endpoints	**Primary**: Statistically significant abdominal circumference and fat reduction post SlimShape treatment at the final follow-up compared to baseline, based on tape measurements and ultrasound imaging. **Secondary**: - Correct identification of the pre- and post-treatment photos as demonstrated in at least 70% or greater of treated subjects. - Abdominal circumference reduction at each visit, based on tape measurements. - Abdominal fat reduction at each visit, measured by Ultrasound. - Subject's self-assessment for satisfaction and recommendation. - Subject satisfaction self-assessment. - Subject's discomfort (pain) level after each treatment.
Effectiveness Results	**Primary**: Met endpoint; Both the midline reduction in abdominal circumference and the reduction in abdominal fat layer were statistically significant at the final follow-up compared to baseline. **Secondary**: - The blinded reviewers assessed correctly 86% of the photographs. - The amount of circumference reduction was statistically significant compared to baseline at each visit, as well as at the upper and lower abdomen. - The majority of the subjects were satisfied (53% at treatment 3, 62% at 4 week follow up, 59% at 8 week follow up and 59% at 12 week follow up). - Most of the subjects reported they will recommend this procedure (75%, 76%, 76% and 77% reported they recommended at treatment 3, 4, 8 and 12 weeks follow up, respectively). - Most subjects (91%) reported none to moderate pain for each treatment.
Safety Results	There were no reports of serious or unanticipated adverse events, with 8 mild adverse events after 144 treatments. No subjects discontinued from the study due to adverse events. The immediate responses included erythema and edema, which resolved completely within several hours without any intervention.

Histology data from a study of 11 healthy subjects further confirm the safety profile of the device. The study results demonstrated that treatment consistently demonstrated discrete areas of fat necrosis within the subcutaneous tissue. The effect is present solely in the subcutaneous tissue, while the dermal and epidermal layers are intact with no adverse skin events.

Therefore, clinical evaluation of the SlimShape device demonstrated the favorable performance and safety profile of the device for lipolysis of the abdomen and non-invasive reduction of the circumference. Results thus further support substantial equivalence of the device compared to the predicate.

Conclusions

The SlimShape has the same intended use and similar indications for use, technological characteristics and principles of operation as its predicate device. Performance data demonstrate that the differences between the SlimShape and the predicate do not raise new

types of safety or effectiveness questions. Clinical studies of the SlimShape have demonstrated the safety and effectiveness profile of the device in the intended population.

Thus, the SlimShape is substantially equivalent to the predicate device.