510(k) SUMMARY

Syneron Medical Ltd.'s Contour I System

APR 10 2014

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

Contact Person: Ruthie Amir, MD, Global Vice President of Clinical Affairs

Date Prepared: April 7, 2014

Name of Device

Syneron Contour I V3.1 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 Devices

Medicis Technologies Corporation LipoSonix System Model 2 (K112626)

Intended Use / Indications for Use

The Contour I V3.1 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 Contour I is comprised of multiple components, including the control unit and ultrasonic transducer. The Contour I V3.1 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 Contour I achieve selective disruption of adipose tissue without damaging neighboring tissues such as blood vessels, nerves, or muscle.

Technological Characteristics

The Contour I V3.1 is comprised of the system console, including the computer, and therapeutic ultrasonic transducer. The transducer delivers the focused ultrasound energy beam to the targeted treatment area, and real-time optical and acoustic feedback on the treatment is provided via the tracking and guidance system. The transducer functionality is based on the piezoelectric ceramic acoustics core in the transducer.

Performance Data

The following nonclinical performance testing was conducted to support the substantial equivalence of the Contour I 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 Contour I 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, at a focal depth highly similar to that of the predicate device.
- Acoustic power testing demonstrated that the acoustic power of the transducers is highly predictable with low variability.
- In vitro acoustic and thermal measurements and computational modeling 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.
- Electromagnetic compatibility (IEC 60601-1, IEC 60601-1-2) and electromagnetic immunity testing was conducted and demonstrated the electrical safety of the device. Electrical and mechanical safety of the device was evaluated per the related clauses of IEC 60601-2-37.
- In vivo and ex vivo testing in the animal model was performed. In addition, ex vivo testing on the Contour I family of devices demonstrated the treatment effects of the Contour I, and supported its safety and efficacy profile for the intended use.

In addition, clinical evaluation of the device in the intended population was performed in a multicenter, randomized, controlled study. The study evaluated the safety and effectiveness of the Contour I V3.1 in abdominal circumference reduction relative to no treatment (control) in 150 subjects (safety population) separated into two groups; 118 subjects were included in Group 1 and 32 subjects were included in Group 2. The safety analysis included all subjects for whom a Device or Control procedure was initiated (i.e., after randomization), including subjects from both Group 1 and Group 2. Subjects randomized into Group 1 underwent three study phases—control, treatment, and follow-up. The control phase and device phase

results for each Group 1 subject were compared to evaluate the device effect compared to the control phase (no device) in reducing abdominal circumference. Comparatively, subjects randomized to Group 2 underwent two study phases—treatment and follow up (i.e., no control). Group 2 subjects were included in the study to blind the assessor to the subject's treatment group at the time of circumference measurement, and the primary and secondary confirmatory analyses of the study were based on Group 1 data only. To further ensure blinding and to minimize the potential for bias, the individual measuring the subject's abdominal circumference was not the same person who treated the subject, and was blinded to the subject's treatment group.

Group 2 subjects received device treatment for four weeks (device phase) while Group 1 subjects received no treatment for six weeks (control phase) followed by treatment for four weeks; subjects in both groups were measured at the same time points, i.e., evefy two weeks. After the first four weeks, Group 2 ended its treatment phase while Group 1 began treatment for four weeks. During Group 1's treatment phase, subjects' abdomen circumferences continued to be measured every 2 weeks in both groups. At the end of Group 1's treatment phase, both groups continued to be measured for an additional 3 months (12 weeks). During these 3 months (12 weeks) of follow up, measurements were performed every 4 weeks in both groups.

The study included subjects between age 18 and 65 who met all inclusion criteria and none of the exclusion criteria. The majority of study subjects were Caucasian females of skin types II through IV. Mean age was 44.6 years. Baseline measurements for the study subjects measured 2.7 cm in mean abdominal fat thickness, 95.1 cm in horizontal midline circumference, 69.6 kg in mean weight, and 25.5 kg/m^2 in average BMI. The primary effectiveness endpoint measured the difference between the change in circumference for device and control phases of the intent to treat (ITT) primary endpoint population (n=109) relative to the protocol-specified clinically meaningful threshold of -1.5 cm. Two secondary endpoints were also assessed in the study: response rate in comparison to a clinically significant reduction (defined as -1.5 cm), and circumference reduction results achieved in the population of subjects who maintained stable weight during the control phase of the study. The safety endpoint assessed all adverse events and serious adverse events occurring during the study.

The study results for the primary endpoint demonstrated an average circumference reduction of -2.0 cm, which was statistically significant compared to the threshold of -1.5 cm (p=0.0464), as shown in the table below.

Parameter	Mean (cm)	Median	Lower 95% CL	Upper 95% CL	N	P-Value of Comparison to -1.5 cm
Change in Circumference in Control Phase	-0.48	-0.30	-0.75	-0.22	93	
Change in Circumference in Device Phase	-2.51	-2.0	-2.94	-2.09	93	
Difference between Control and Device Phases in Circumference Reduction	-2.02	-1.7	-2.53	-1.52	93	0.0464

Further, when using analysis of covariance (ANCOVA), results continued to confirm the circumference reduction results observed in the primary endpoint analysis. Based on this model adjusting for weight change in the ITT population, the Contour I treatment effect (mean circumference reduction of -1.9 cm) remained statistically significant (p=0.002) and its 95% upper confidence limit was at -1.7 cm, which exceeded the minimum threshold reduction of -1.5 cm.

Results for the secondary endpoints and sensitivity analyses also supported the circumference reduction effects with Contour I treatment. With all missing data imputed with a zero reduction, the effect of device treatment on circumference reduction remained greater than -1.5 cm. The treatment was administered without anesthetic, and subjects reported a low level of pain. No device related serious adverse events were reported and most adverse events were non-serious and resolved after no or remedial treatment.

Substantial Equivalence

The Contour I has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The technological differences between the Contour I and its predicate device mainly consist of differences in ultrasonic frequencies. However, the devices present comparable energy densities, total energy doses, and focal depths. Further, the additional tracking and guidance feature with the Contour I device is designed to contribute to the overall safety profile of the device. Therefore, the technological differences between the Contour I and its predicate device do not raise any new types of safety or effectiveness questions. Nonclinical and clinical studies of the Contour I have evaluated the performance of the Contour I. Thus, the Contour I is substantially equivalent.

Conclusion

Syneron's Contour I V3.1 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 Contour I V3.1 device is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

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

Re: K133238
Trade/Device Name: Syneron Contour I V3.1 System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV
Dated: March 4, 2014
Received: March 4, 2014

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 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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)*

K133238

Device Name

Contour I v3.1 System

Indications for Use *(Describe)*

The Contour I V3.1 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."