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

September 26, 2017

Cynosure, Inc.
Amy Tannenbaum
Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K171992
Trade/Device Name: SculpSure
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: June 30, 2017
Received: July 3, 2017

Dear Amy Tannenbaum:

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 (DICE) 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 (DICE) 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 -S3

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)*
Kpending

Device Name
SculpSure™

Indications for Use *(Describe)*
The Cynosure SculpSure™ is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for non-invasive lipolysis of the submental area in individuals with a BMI of 43 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs and submental area.

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 for SculpSure Laser System

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) Submitter Information	
Applicant	Cynosure, Inc.
Address	5 Carlisle Road Westford, MA 01886
Phone Number	(978) 256-4200
Fax Number	(978) 256-6556
Establishment Registration Number	1222993
Contact Person	Amy Tannenbaum
Preparation Date	June 30, 2017
807.92(a)(2) Name of Device	
Trade or Proprietary Name	SculpSure
Common or Usual Name	Laser
Classification Name	Laser for disruption of adipocyte cells for aesthetic use
Classification Panel	General & Plastic Surgery
Regulation	21 CFR 878.5400
Regulatory Class	II
Product Code(s)	PKT
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Devices	Cynosure SculpSure K171111, Zeltiq Coolsculpting K162050 The predicate devices have not been subject to a design-related recall
807.92(a)(4) Device Description	
	The Cynosure SculpSure is a diode laser system. The main components of SculpSure are a console and four applicators that deliver the laser energy to the patient. Electrically efficient semiconductors generate optical radiation (1060 nm) which is used to deliver laser energy to subcutaneous tissue layers.
807.92(a)(5) Intended Use of the Device	
	The SculpSure laser system is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for non-invasive lipolysis of the submental area in individuals with a Body Mass Index (BMI) of 43 or less. The device is intended to affect the appearance of visible fat bulges in

	the abdomen, flanks, back, thighs, and submental area.

807.92(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate

	Proposed SculpSure Laser System	**Cynosure SculpSure Laser System**	**Zeltiq Coolsculpting Device**
510(k) Number	KPending	K171111	K162050
Manufacturer	Cynosure, Inc.	Cynosure, Inc.	Zeltiq Aesthetics, Inc.
Lipolysis Method	Heat-assisted	Heat-assisted	Cold-assisted
Device Type	Diode Laser	Diode Laser	N/A
Wavelength	1060 ±20 nm (infrared)	1060 ±20 nm (infrared)	N/A
Spot Size	4 x 6 cm^2 on each of the Applicator heads (up to four applicators per body treatment) 14.28 cm^2 (one applicator head and frame used for Submental treatment)	4 x 6 cm^2 on each of the Applicator heads (up to four applicators per treatment)	4.5 x 7 cm^2 (2x) approximate
Pulse Width (laser ON time)	CW	CW	N/A
Power Density	Up to 1.4 W/cm^2 (body) Up to 2.35 W/cm^2 (submental)	Up to 1.4 W/cm^2	N/A
Attachment to patient	Belt (body treatment) Headgear and straps (submental treatment)	Belt (body treatment only)	Belt
Voltage	200-240V~, Single Phase	200-240V~, Single Phase	N/A
Current	20A	20A	N/A

807.92(b)(1) Non-clinical tests submitted

Software verification and validation was performed, and it was demonstrated that the software performs as intended. Testing confirmed that the power output meets specification. Electromagnetic compatibility and electrical safety testing was performed per standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22 and IEC 60825-1. Results confirmed the device meets the standards. All patient contacting materials were assessed as per ISO 10993-1 and found to be biocompatible. Additional bench testing was performed to demonstrate that the submental mask provides beam uniformity to the treatment area within +/- 15% specification.

807.92(b)(2) Clinical tests submitted

A prospective, controlled study was conducted at 3 study centers to evaluate the safety and efficacy of Cynosure SculpSure laser for the non-invasive fat reduction of the submental area. The treatment techniques used and subsequent follow up schedule for the study were kept consistent between the three studies. 57 subjects were enrolled in the study. 23 of the subjects had a BMI of less than 30, and 34 subjects had a BMI of 30 or higher. Each subject received up to 2 treatments with SculpSure at the submental area. There were 5 patients that received 1 treatment, and the rest received 2 treatments. Treatment effectiveness was assessed through blind evaluation of pre- and post- final treatment (12 week) photographs; percentage change in the adipose tissue thickness from baseline to 12 week follow up measured through ultrasound imaging; and patient satisfaction measured at the 12 week post- final treatment follow up visit through 6 point Likert scale. On an average, blind evaluators were able to identify 93% (51/55) of the post treatment photographs; ultrasound imaging at 12 week post follow up visit showed 15.2% (1.785mm) normalized fat reduction and patient satisfaction survey at 12 week post follow up visit showed 100% (55/55 subjects) satisfaction rate. All subjects that were treated in the study (N=57) were included in the safety analysis and adverse events were assessed at all visits. The side effects that were reported were swelling, pain, nodules, redness, hardness, numbness, hair loss, itching, bruising, and blisters. All events, except for one, were transient and the majority were mild or moderate in nature. There was no significant difference between the safety and efficacy results of the subjects that had a BMI below 30 as compared to the safety and efficacy results of the subjects that had a BMI of 30 or above. The study concluded that the SculpSure is safe and effective for non-invasive fat reduction at the submental area.

807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted

Cynosure believes that SculpSure is substantially equivalent to its predicate devices with same intended use and similar technological characteristics. The non-clinical data for SculpSure supports the safety of the device and the biocompatibility, hardware and software verification and validation demonstrate that the SculpSure should perform as intended in the specified use conditions. Additionally, the successful clinical performance of SculpSure as documented in clinical study demonstrate that the SculpSure has a safety and effectiveness profile that is similar to its predicate devices. Therefore, Cynosure is requesting clearance for treatment of the submental area.