January 3, 2019

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

Re: K182741
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: September 27, 2018
Received: September 28, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182741

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 49 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs and submental area. When using the petite mask for non-invasive lipolysis of the submental area, the device can also affect the appearance of lax tissue in the 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.

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

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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	September 27, 2018
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 K171992, Zeltiq Coolsculpting K172144 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 49 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs, and submental area. When using the petite mask for non-invasive lipolysis of the submental area, the device can also affect the appearance of lax tissue in the 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	K171992	K172144
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 (for standard submental mask) 10.49 cm^2 (for petite submental mask)	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)	4.5 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 3.06 W/cm^2 (submental)	Up to 1.4 W/cm^2 (body) Up to 2.35 W/cm^2 (submental)	N/A
Attachment to patient	Belt (body treatment) Headgear and straps (submental treatment)	Belt (body treatment) Headgear and straps (submental treatment)	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

Electromagnetic compatibility and electrical safety was performed per standards IEC 60601-1, Ed 3.1, IEC 60601-1-2 Ed 4, IEC 60601-2-22, Ed 3.1, and IEC 60825-1 Ed 2. Software has been updated and validation was performed. 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 petite submental mask provides beam uniformity to the treatment area with +/- 15% specifications.

807.92(b)(2) Clinical tests submitted

A controlled clinical study was conducted to evaluate the safety and efficacy of treatment in the submental area for adipose tissue reduction using the petite mask.

A prospective, controlled study was conducted at 3 study centers to evaluate the safety and efficacy of the Cynosure SculpSure laser for the non-invasive fat reduction of the submental area, using the new petite mask (10.49cm^2). The treatment techniques used and subsequent follow up schedule for the study were kept consistent between the three centers. 61 subjects enrolled in the study. 34 subjects had a BMI of less than 30, and 27 subjects had a BMI of 30 or higher. Each subject received up to 2 treatments with the petite mask in the submental area. There were 4 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; significant change in 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. In addition, an analysis of the safety and adverse events will be conducted. On average, blind evaluators were able to identify 91% (53/58) of all post-treatment photograph. Reduction in adipose tissue was measured by ultrasound imaging at 12-week post follow up visit. Results showed a p-value of <0.001 for all subjects indicating a statistically significant reduction in adipose tissue layer, with average reduction of 1.4mm. Therefore, the secondary efficacy endpoint for statistically significant reduction in adipose tissue was met. The patient satisfaction survey at 12-week post follow up visit showed a 91% (53/58) satisfaction rate. All subjects that were treated in the study (n=61) were included in the safety analysis and adverse events were assessed at all visits. Most events were transient, and a majority was mild in nature. Both the High and Low BMI groups met all three endpoints to prove safety and efficacy of this study. There was no significant difference between the safety and efficacy results of the subjects that had a BMI above 30 as compared to the results of the subjects that had a BMI below 30. This study concluded that the SculpSure is safe and effective for non-invasive fat reduction at the submental area using the petite mask.

In addition, an evaluation of the effectiveness of the SculpSure device to affect the appearance of lax skin in the submental area was conducted.

A prospective, controlled study was conducted at 3 study centers to evaluate the safety and efficacy of the Cynosure SculpSure laser to improve the appearance of lax tissue in the submental area, using the submental mask. In this study, the petite (10.49cm^2) mask was used. The treatment techniques used and subsequent follow up schedule for the study were kept consistent between the three centers. 61 subjects were enrolled in the study. 34 subjects had a

BMI of less than 30, and 27 subjects had a BMI of 30 or higher. Each subject received up to 2 treatments with the petite mask in the submental area. There were 4 patients that received 1 treatment, and the rest received 2 treatments. Treatment effectiveness was assessed through the reduction in submental area and neck lax tissue as measured by photographic analysis at the 12-week post-final treatment follow up, and subject questionnaire on 'chin toning' given at the 12-week post-final treatment follow up. Anatomical points were identified on the images and analyzed using the same protocol as described by Oni, G, Hoxworth R, Teotia, S, et al. Evaluation of a Microfocused Ultrasound System for Improving Skin Laxity and Tightening in the Lower Face. *Aesthetic Surgery Journal* 2014;34(7):1099-1110. Criteria for improvement was a $\geq 20mm^2$ decrease in lax tissue. 86% of subjects (50/58) showed a measurable improvement in lax tissue in the submental area. 86% (49/57) patients responded that they agreed that the treatment made their chin look more toned. All subjects that were treated in the study (n=61) were included in the safety analysis and adverse events were assessed at all visits. Most events were transient, and a majority was mild in nature. Both the High and Low BMI groups met all three endpoints to prove safety and efficacy of this study. There was no significant difference between the safety and efficacy results of the subjects that had a BMI above 30 as compared to the results of the subjects that had a BMI below 30. This study concluded that SculpSure is safe and effective to affect the appearance of lax tissue in 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 technological characteristics. The non-clinical data for SculpSure, including biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. Additionally, the successful clinical performance of the SculpSure with the petite submental mask proves that the safety and efficacy profile meet that of the predicate devices. Therefore, Cynosure is requesting clearance for use of the petite mask and the indication to affect the appearance of lax tissue in the submental area.