CynoSure, Inc.
Aastha Kohli
Senior Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

August 11, 2022

Re: K160470
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

Dear Aastha Kohli:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 21, 2016. Specifically, FDA is updating this SE Letter to remove OOK as an administrative correction, because OOK (Dermal Cooling Pack/Vacuum/Massager) does not apply to your device.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Long Chen, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-6389, Long.Chen@fda.hhs.gov.

Sincerely,

Long H. Chen -S
Digitally signed by Long H. Chen -S
Date: 2022.08.11 13:59:36 -04'00'

Long Chen, Ph.D.
Director (Acting)
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

July 21, 2016

CynoSure, Inc.
Ms. Aastha Kohli
Senior Regulatory Affairs Specialist
5 Carlisle Road
Westford, MA 01886

Re: K160470
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, OOK
Dated: June 14, 2016
Received: June 15, 2016

Dear Ms. Kohli:

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 Parts 801 and 809); 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" (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 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,

Christopher J. Ronk -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 below.

510(k) Number *(if known)*
K160470

Device Name
Sculpsure

Indications for Use *(Describe)*
Cynosure SculpSure is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen and flanks.

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.

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."

Section 5 – 510(k) Summary

Section 5	510(k) Summary

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) 367-8736
Fax Number	(978) 256-6556
Establishment Registration Number	1222993
Contact Person	Kevin O'Connell
Preparation Date	July 18, 2016
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 K150724, K150230 Zeltiq Coolsculpting K151179 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 Cynosure SculpSure is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to

	affect the appearance of visible fat bulges in the abdomen and flanks.

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	Pending	K150230, K150230	K151179
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)	1064 ± 25nm (infrared)	N/A
Spot Size	4 x 6 cm^2 on each of the Applicator heads	4 x 6 cm^2 on each of the Applicator heads	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	Up to 1.4 W/cm^2	N/A
Attachment to patient	Belt	Belt	Belt
Voltage	200-240V~, Single Phase	120V	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.

807.92(b)(2) Clinical tests submitted

Not applicable, no change in indication for use.

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.