



June 22, 2023

Shanghai Bele Medical Technology Co.,Ltd  
Jeremy Li  
General Manager  
Room 402, 4F, Building 1, No.3255 Shengang Road, Songjiang  
District  
Shanghai, Shanghai 201600  
China

Re: K231131

Trade/Device Name: Diode Laser Body Sculpture Systems  
Regulation Number: 21 CFR 878.5400  
Regulation Name: Low Level Laser System For Aesthetic Use  
Regulatory Class: Class II  
Product Code: PKT  
Dated: March 24, 2023  
Received: April 21, 2023

Dear Jeremy Li:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Jianting Wang -S

Jianting Wang  
Acting Assistant Director  
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

Enclosure

## Indications for Use

510(k) Number (if known)  
K231131

Device Name  
Diode Laser Body Sculpture Systems

Indications for Use (Describe)

This product 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. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.

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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**Section 3-510(k) summary** K231131**I Submitter**

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**Contact Person**

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**II Proposed Device**

Trade Name of Device: Diode Laser Body Sculpture Systems

Common name: Low Level Laser System for Aesthetic Use

Regulation Number: 21 CFR 878.5400

Regulatory Class: Class II

Product code: PKT

Review Panel: General &amp; Plastic Surgery

**III Predicate Devices**

510(k) Number: K182741

Trade name: SculpSure

Common name: Low Level Laser System for Aesthetic Use

Classification: Class II

Product Code: PKT

Manufacturer: Cynosure

**IV Device description**

The BL-A10 is a 1060nm Diode Hyperthermic Laser Lipolysis system and is the latest technology for non-invasive body contouring. It applies a 1060nm wavelength laser to target the adipose tissue to reduce fat in areas such as flank and abdomen.

The purpose of the device is to breakdown the fat cells in the target area and in doing so contour the body and reduce the number of fat cells in that area. It is designed to meet international safety and performance standards.

**V Indication for use**

This product 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. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.

**VI Comparison of technological characteristics with the predicate devices**

Item	Proposed device	Predicate device (K182741)	Discussion
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Product Code	PKT	PKT	Identical
Regulation No.	21 CFR 878.5400	21 CFR 878.5400	Identical
Class	Class II	Class II	Identical
Indication for use	<p>This product 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. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.</p>	<p>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.</p>	Equivalent
Laser type	Diode laser	Diode laser	Identical
Wavelength	1060nm±20 nm (infrared)	1060nm±20 nm (infrared)	Identical
Lipolysis method	Heat-assisted	Heat-assisted	Identical
Spot size	4 * 6 cm <sup>2</sup> on each of the Applicator heads (up to four applicators per body treatment)	4 * 6 cm <sup>2</sup> on each of the Applicator heads (up to four applicators per body treatment)	Equivalent

		14.28 cm <sup>2</sup> (for standard submental mask) 10.49 cm <sup>2</sup> (for petite submental mask)	
Pulse width	CW	CW	Identical
Power density	0.6~1.6W/cm <sup>2</sup>	Up to 1.4 W/ cm <sup>2</sup> (body) Up to 3.06 W/ cm <sup>2</sup> (submental)	Similar
Attachment to patient	Belt	Belt	Identical
Voltage	AC110-240V, 16-4A , 50/60Hz.	AC200-240V, 50/60Hz, 20A	Equivalent
Peak power	35W (per applicator)	30W (per applicator)	Equivalent
Cooling	Contact cooling	Contact cooling	Identical

## VII Non-Clinical Testing

A series of tests have been performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

### Electrical safety and electromagnetic compatibility

- IEC 60601-1 : 2005+A1 : 2012+A2 : 2020 / EN 60601-1: 2006+A1: 2013+A12:2014+A2:2021 Medical electrical equipment. General requirements for basic safety and essential performance
- IEC60601-1-2:2014+A1:2020 / EN 60601-1-2:2015+A1:2021 Medical electrical equipment - part 1-2 General requirements for basic safety and performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-22:2019/EN 60601-2-22:2020 Medical electrical equipment – part 2-22: Particular requirements for basic essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014/EN 60825-1:2014 Safety of laser products-Part 1:Equipment classification and requirements

### Biocompatibility Evaluation:

Per FDA's Biocompatibility Guidance issued on September 04, 2020 and with regard to Table A.1 Evaluation Tests for consideration in ISO, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" " the following tests performed on the material which contacts with human for Biocompatibility:

- Cytotoxicity;
- Skin irritation;

- Skin Sensitization.;

### **VIII Clinical Testing**

It is not applicable.

### **IX Conclusion**

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.