September 10, 2020

Shanghai Apolo Medical Technology Co., Ltd.
Mr. Felix Li
RA Supervisor
Room 301-310, Building 11, No.388, Yindu Road,
Xuhui District
Shanghai, Shanghai 200231
China

Re: K201731
Trade/Device Name: Diode Laser Body Sculpture System
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: June 18, 2020
Received: June 24, 2020

Dear Felix 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201731

Device Name
Diode Laser Body Sculpture Systems

Indications for Use *(Describe)*
The Diode Laser Body Sculpture Systems 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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K201731-510(k) summary

I Submitter

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Date of preparation: Sep 9th, 2020

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 & 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

510(k) Number:	K191068
Trade name:	Powersculp laser lipolysis system
Common name:	Low Level Laser System for Aesthetic Use
Classification:	Class II
Product Code:	PKT
Manufacturer	Wuhan Lotuxs Technology Co., Ltd.

IV Device description

The HS-851 Diode Laser Body Sculpture Systems is a 1060nm Diode Hyperthermic Laser Lipolysis system and utilizes the latest technology for non-invasive body contouring. It applies a 1060nm wavelength laser to target the adipose tissue to reduce stubborn fat in areas such as flank, abdomen, back and thighs.

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.
The proposed device consists of the main unit, control unit with dedicated software and user interface, and the treatment applicators.

V Indication for use

The Diode Laser Body Sculpture Systems 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	Primary predicate device (K182741)	Secondary predicate device (K191068)	Discussion
Product Code	PKT	PKT	PKT	Identical
Regulation No.	21 CFR 878.5400	21 CFR 878.5400	21 CFR 878.5400	Identical
Class	Class II	Class II	Class II	Identical
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	The Cynosure SculpSure™ is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass	The Powersculp laser lipolysis system is intended for non-invasive lipolysis of the flank and abdomen to achieve disruption of	Equivalent

	device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.	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.	adipocyte celles intended for non-invasive aesthetic use to achieve a desired aesthetic effect. This treatment is intended for individuals with a Body Mass Index (BMI) of 30 or less.	
Laser type	Diode laser	Diode laser	Diode laser	Identical
Wavelength	1060nm±20 nm (infrared)	1060nm±20 nm (infrared)	1060nm±20 nm (infrared)	Identical
Lipolysis method	Heat-assisted	Heat-assisted	Heat-assisted	Identical
Spot size	4 * 6 cm^2/4 * 8 cm^2 on each of the Applicator heads (up to four	4 * 6 cm^2 on each of the Applicator heads (up to four	4 * 8 cm^2 (A single applicator of four applicators)	Equivalent

	applicators per body treatment)	applicators per body treatment) 14.28 cm^2 (for standard submental mask) 10.49 cm^2 (for petite submental mask)		
Pulse width	CW	CW	CW	Identical
Power density	0.8 ~ 1.6W/cm^2	Up to 1.4 W/ cm^2 (body) Up to 3.06 W/ cm^2 (submental)	Up to 0.7-1.7W/ cm^2	Equivalent
Attachment to patient	Belt	Belt	Belt	Identical
Voltage	AC110-240V, 50/60Hz, 20-4A	AC200-240V, 50/60Hz, 20A	AC100-240V, 50/60Hz, 15A	Equivalent
Peak power	35W (per applicator) for 4 * 6 cm^2 50W (per applicator) for 4 * 8 cm^2	30W (per applicator)	50W (per applicator)	Equivalent
Cooling	Contact cooling	Contact cooling	Contact cooling	Identical

VII Non-Clinical Testing

A series of tests have been performed to verity 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+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -Part 1-2: General

requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements
- IEC 60601-2-22:2007(third edition)+A1:2012 for use in conjunction with IEC 60601-1:2005 (third edition)+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Biocompatibility Evaluation:

Per FDA's Biocompatibility Guidance issued on June 16, 2016 and with regard to Table A.1 Evaluation Tests for consideration in ISO, "Use of international Standard ISO 10993-1, Biological evaluation of medical - 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.