July 17, 2019

Wuhan Lotuxs Technology Co., Ltd.
℅ Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, China 511660

Re: K191068
Trade/Device Name: Powersculp laser lipolysis system
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: April 22, 2019
Received: April 22, 2019

Dear Jinghua Zhou:

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,

for

Neil Ogden
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* K191068

Device Name
Powersculp laser lipolysis system

Indications for Use *(Describe)*
The Powersculp laser lipolysis system is intended for non-invasive lipolysis of the flank and abdomen to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. This treatment is intended for individuals with a Body Mass Index (BMI) of 30 or less.

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 5 - 510(k) Summary

K191068

Date of Summary Preparation: April 15, 2019

1. Submitter's Identifications

Submitter's Name: Wuhan Lotuxs Technology Co., Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Laser for disruption of adipocyte cells for aesthetic use
Product Name: Low level laser system for aesthetic use
Trade Name: Powersculp laser lipolysis system
Model: PSP050
Classification Panel: General & Plastic Surgery
Product Code: PKT
Regulation Number: 21 CFR 878.5400
Device Classification: Class II

4. The Predicate Devices

Primary Predicate device: K160470 SculpSure
Secondary predicate device: K150230 Sculpsure

5. Device Description

The Powersculp laser lipolysis system is a diode laser system. Electrically efficient semiconductors generate optical radiation (1060 nm) which is used to deliver laser

energy to subcutaneous tissue layers. The Powersculp laser lipolysis system is capable of peak powers of 50W. The main components of Powersculp laser lipolysis system are a console and four applicators.

6. Intended Use of Device

The Powersculp laser lipolysis system is intended for non-invasive lipolysis of the flank and abdomen to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. This treatment is intended for individuals with a Body Mass Index (BMI) of 30 or less.

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Primary predicate device	Secondary predicate device	Comparison
510k Number	-------	K160470	K150230	------
Product Code	PKT	PKT	PKT	Same
Proprietary Name	Powersculp laser lipolysis system	Sculpsure	Sculpsure	------
Model	PSP050	/	/	------
Manufacturer	Wuhan Lotuxs Technology Co., Ltd.	Cynosure, Inc.	Cynosure, Inc.	------
Indications for use	The Powersculp laser lipolysis system is intended for non-invasive lipolysis of the flank and abdomen to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. This treatment is intended for individuals with a Body Mass Index (BMI) of 30 or less.	The Cynosure SculpSure is a diode laser system intended for noninvasive 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.	The Cynosure SculpSure is intended for non-invasive lipolysis of the flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. Intended for individuals with a Body Mass Index (BMI) of 30 or less.	Same The indications for use of the proposed device are same as those of predicate device K160470 and K150230.
Operating theory	The Powersculp laser lipolysis system is a diode laser system. Electrically efficient	The Cynosure SculpSure is a diode laser system. The main components of	The Cynosure SculpSure is a diode laser system. Electrically efficient	Same Although there are differences in expression

	semiconductors generate optical radiation (1060 nm) which is used to deliver laser energy to subcutaneous tissue layers. The Powersculp laser lipolysis system is capable of peak powers of 50W. The main components of Powersculp laser lipolysis system are a console and four applicators.	SculpSure are a console and four applicators that deliver the laser energy to the patient. Electrically efficient semiconductors generate opticalradiation (1060 nm) which is used to deliver laser energy tosubcutaneous tissue layers.	semiconductors generate optical radiation (1064 nm) which is used to directly irradiate the skin's surface. The Sculpsure is intended for noninvasive lipolysis of the flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect.	among the three devices, the technical principles are essentially the same.
Structure and main components	The main components of Powersculp laser lipolysis system are a console and four applicators.	The main components of SculpSure are a console and four applicators.	The main components of SculpSure are a console and applicator.	Same The main components of the proposed device are same as those of the primary predicate device K160470.
Laser type	diode laser	diode laser	diode laser	Same
Lipolysis method	Heat-assisted	Heat-assisted	Heat-assisted	Same
Wavelength	1060nm±20 nm (infrared)	1060 ±20 nm (infrared)	1064nm	Same
Spot size	4 × 8 cm^2 (A single applicator of four applicators)	4 × 6 cm^2 on each of the applicator heads (4X)	4 × 6 cm^2 (3X)	Similar The amount of applicator is same between the primary predicate device K160470 and the proposed device.

				The spot size of applicator does not affect the safety and effectiveness.
Pulse Width (laser ON time)	CW	CW	CW	Same
Power density	Up to 0.7-1.7W/ cm^2	Up to 1.4 W/cm^2	1.7W/ cm^2	Similar The power density of the proposed device is customizable, and the maximum power density is same as the secondary predicate device K150230, so this defference is not affect safety and effectiveness.
Power supply	AC100-240V, 50/60Hz, 15A	200-240V~, Single Phase, 20A	120V, 20A	Similar The power supply is different, not affect safety and effectiveness.
Peak power	50W (per applicator)	30W (per applicator)	40W (per applicator)	Similar The peak power is different, which related to power density and spot size. The difference does not affect safety and effectiveness.

Cooling	Contact cooling	Contact cooling	Contact cooling	Same
Attachment to patient	belt	belt	belt	Same
Software control	Yes	Yes	Yes	Same
Electromagnetic compatibility and electrical safefy compliance	IEC 60601-1-2 ANSI AAMI ES60601-1 IEC 60825-1 IEC 60601-2-22	IEC 60601-1-2 ANSI AAMI ES60601-1 IEC 60825-1 IEC 60601-2-22	IEC 60601-1-2 ANSI AAMI ES60601-1 IEC 60825-1 IEC 60601-2-22	Same
Discussion for Substantially Equivalent (SE)	The proposed device PSP050 has the same as the predicate device: indications for use, operating theory, structure and main components, laser type, lipolysis method, wavelength, power width, cooling method, attachment to patient. The differences only exist in such contents: spot size, power density, power supply, peak power that both can be controlled in range of application. These minor differences between proposed device and predicate device raise no new issue of safety and effectiveness. According to the non-clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.			

8. Non-Clinical Tests Submitted:

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Testing confirmed that the power output meets specification. Electromagnetic compatibility and electrical safety testing was performed per standards ANSI AAMI ES60601-1, 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.

9. Clinical Tests Submitted:

According to "8. Clinical Testing" of "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use", and operating instruction and "7. Summary of Substantial Equivalence" submitted of the proposed device, the proposed device PSP050 is Substantially Equivalent (SE) to the predicate device, includes: indication for use, design (such as operating theory, structure and main component, software control), technology (such as laser type, lipolysis method, wavelength, power width, cooling method, attachment to patient), the non-clinical tests complied with the requirements of relevant recognized standards, and passed the bench tests (such as performance tests, storage condition tests), so Lotuxs belives that the proposed device Powersculp laser lipolysis system PSP050 does not need to carry out clinical tests, and the clinical study data that have been the legally marketed device can be used for reference.

10. Conclusions drawn from clinical and non-clinical tests submitted:

Lotuxs believes that Powersculp laser lipolysis system PSP050 is substantially equivalent to its predicate devices with same indications for use, similar technological characteristics. The non-clinical data for Powersculp laser lipolysis system PSP050 supports the safety of the device and the biocompatibility, hardware and software verification and validation demonstrate that the Powersculp laser lipolysis system PSP050 should perform as intended in the specified use conditions.

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