July 30, 2021

Lotuxs Medtech (Suzhou) Co., Ltd.
Na Wu
QA Manager
RM301, NW-06, Nanopolis Suzhou, 99 Jinji Lake Avenue,
Suzhou Industry
Suzhou, Jiangsu 215123
China

Re: K211402
Trade/Device Name: Powersculp laser lipolysis system
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
878.5650
Regulatory Class: Class II
Product Code: PKT
Dated: May 6, 2021
Received: May 6, 2021

Dear Na Wu:

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
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)*

K211402

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.

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."

Lotuxs Medtech (Suzhou) Co., Ltd.

Section 5 - 510(k) Summary

Date of Summary Preparation: April 30, 2021

1. Submitter's Identifications

Submitter's Name: Lotuxs Medtech (Suzhou) Co., Ltd.
Address: RM301, NW-06, Nanopolis Suzhou, 99 Jinji Lake Avenue, Suzhou Industry Park, Suzhou 215123, China
Contact Person: Na Wu
Contact Title: QA Manager
Contact Email Address: na.wu@lotuxs.com
Telephone: +86-0512-6288 0553

2. Correspondent's Identifications

Correspondent's Name: Lotuxs Medtech (Suzhou) Co., Ltd.
Address: RM301, NW-06, Nanopolis Suzhou, 99 Jinji Lake Avenue, Suzhou Industry Park, Suzhou 215123, China
ZIP Code: 215123
Contact Person: Na Wu
Contact Title: QA Manager
Contact E-mail Address: na.wu@lotuxs.com
Telephone: +86-0512-6288 0553

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: PSP100
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: K191068 Powersculp laser lipolysis system

5. Device Description

PowerSculp laser lipolysis system is a diode laser system that emits laser radiation centered at 1064nm in order to achieve non-invasive laser lipolysis. Main components of the device include the laser console with display and controls, and four cooled laser applicators that attach to frames and a belt that is attached to the person being

treated. The device is powered by an alternating current electrical power source.

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. Device Comparison Table

Table 1

	Proposed device	Primary predicate device	Comparison
510k Number	K211402	K191068	------
Product Code	PKT	PKT	Same
Proprietary Name	Powersculp laser lipolysis system	Powersculp laser lipolysis system	Same
Model	PSP100	PSP050	------
Manufacturer	Lotuxs Medtech (Suzhou) Co., Ltd.	Wuhan Lotuxs Technology Co., Ltd.	------
Indications for use	The PowerSculp laser lipolysis system is inten ded for aesthetic use, non-invasive lipolysis of the flank and abdomen to disrupt adipocyte cells thus achieving desired aesthetic effect. This treatment is intended for individuals with a Body Mass Index (BMI) of 30 or less.	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.	Same
Structure and main components	The main components of Powersculp laser lipolysis system are a console and four applicators.	The main components of Powersculp laser lipolysis system are a console and four applicators.	Same
Laser type	diode laser	diode laser	Same
Wavelength	1064nm±20 nm (infrared)	1060 ±20 nm (infrared)	Similar The wavelength of

			proposed device is slightly larger than that of predicate device. It does not affect safety and effectiveness.
Spot size	4 × 8 cm^2 (A single applicator of four applicators)	4 × 8 cm^2 (A single applicator of four applicators)	Same
Pulse Width (laser ON time)	CW	CW	Same
Power density	Up to 0.7-1.7W/ cm^2	Up to 0.7-1.7W/ cm^2	Same
Power supply	AC100-240V, 50/60Hz, 15A	AC100-240V, 50/60Hz, 15A	Same
Peak power	50W (per applicator)	50W (per applicator)	Same
Cooling	Contact cooling	Contact cooling	Same
Attachment to patient	belt	belt	Same
Software control	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	Same

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:

No clinical tests were provided for this pre-market notification.

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

The proposed PowerSculp device utilizes technological characteristics that are the same or are similar to the K191068 predicate device. The proposed device's technological characteristics do not raise new types of questions regarding safety and effectiveness, and the performance testing that was done supports that the proposed device can be used safety and effectively for the proposed indication for use above. Based on the comparison and analysis above, the proposed device is considered to be Substantially Equivalent (SE) to the predicate device.