September 23, 2022

Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
Lily Zhou
Management Representative
2F, Building 11, Lane 1175, Tongpu Rd.
Shanghai, Shanghai 200333
China

Re: K222265
Trade/Device Name: Diosculpt
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: PKT
Dated: November 14, 2021
Received: July 28, 2022

Dear Lily 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,

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

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)*
K222265

Device Name
DioSculpt

Indications for Use *(Describe)*
The DioSculpt laser system 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.

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.

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Date Prepared: Sep. 6th, 2022

510(k) Summary

(As required by 21 CFR 807.92)

I. SUBMITTER

Name of Sponsor:	Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
Address:	2F, Building 11, Lane 1175, TongPu Rd., Shanghai 200333, China
Contact Name:	Lily Zhou
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Fax No.:	0086-021-52827988
Email Address:	laser@wonderful-sh.com

II. DEVICE

Trade Name:	Diosculpt
Common Name:	Low Level Laser for Lipolysis
Model Name:	Diosculpt
Regulation Classification	Low Level Laser System for Aesthetic Use
Product Code:	PKT
Classification Name:	Laser for disruption of adipocyte cells for aesthetic use
Classification Panel:	General & Plastic Surgery
Device Class:	II
Regulation Number:	21 CFR 878.5400

III. PREDICATE DEVICE

The identified predicates within this submission are as follows:

Primary Predicate Device: The Cynosure Sculpsure Low Level Laser System for Aesthetic Use has been cleared by FDA through 510(k) No.K171992 (Decision Date–September 26, 2017).

Secondary Predicate Device: K191068, Powersculp laser lipolysis system, Wuhan Lotuxs Technology Co.,Ltd.(Decision Date-July 17, 2019)

IV. DEVICE DESCRIPTION

The DioSculpt laser lipolysis system is a diode laser system, Electrically efficient semiconductor generate optical radiation (1060nm) which is used to deliver laser energy to subcutaneous tissue layers. DioSculpt's cooling and electical systems assist in maintaining safe and comfortable skin surface temperatures.

V. INDICATIONS FOR USE

The DioSculpt laser system 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.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The subject device in this 510(k) uses the same technology that is utilized in the predicate device. A comparison of technological characteristics is provided in the following table:

510(k) Number	K 222265	K171992	K191068
Lipolysis Method	Heat-assisted	Heat-assisted	Heat-assisted
Device Type	Diode Laser	Diode Laser	Diode Laser
Wavelength	1060±20nm (infrared)	1060±20nm (infrared)	1060±20nm (infrared)
Pulse Width	CW	CW	CW
Energy Density	Up to 1.8W/cm^2	Up to 1.4W/cm^2	Up to 1.7W/cm^2
Spot Size	4*8 cm^2 on each of Applicators	4*6 cm^2 on each of Applicators	4*8 cm^2 on each of Applicators
Peak power per applicator	57.6W	33.6W	50W
Cooling	Self-contained closed loop	Self-contained closed loop	Self-contained closed loop
Attachment to patient	Belt	Belt	Belt

Discussion

The energy density of DioSculpt is 0.1W/cm^2 higher than the predicate device K191068, and the peak power energy is accordingly slightly higher. The higher energy may generate higher temperature to skin. To guarantee the safety, two temperature testing were conducted to measure the four applicators temperature in worst-case scenario and real operation scenario. All testing results do not exceed maximum allowable temperature of 41^{o}C .

The temperature testing result demonstrates the minor difference in energy and peak power per applicator does not raise safety concerns.

VII. NON-CLINICAL TESTING

Biocompatibility testing

The biocompatibility evaluation for DioSculpt was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The applicators are considered tissue contacting, which is categorized as "Surface device", " Intact skin contact", and "with a limited contact duration of less than 24 hours", the following tests were evaluated:

- Skin Sensitization
- In Vitro Cytotoxicity
- Intracutaneous Reactivity

Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on DioSculpt. The system complies with the AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 standards for safety and IEC 60601-1-2:2014 standard for EMC.

Performance Testing

The performance testing were conducted on DioSculpt. The system complied with IEC60601-2-22:2019 and IEC 60825-1:2014.

To guarantee the safety, two temperature testing were conducted to measure the four applicators temperature in worst-case scenario and real operation scenario. All testing results do not exceed maximum allowable temperature of 41°C .

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury, either to patient or to a user of device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, it is concluded, basing on performance testing, indication for use, and technology, the subject device is the same or similar to the predicate device K171992 and K191068.