November 9, 2021

Rohrer Aesthetics, LLC
Mark Rohrer
President
105 Citation Court
Birmingham, Alabama 35209

Re: K212331
Trade/Device Name: BodySculp
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: October 7, 2021
Received: October 12, 2021

Dear Mark Rohrer:

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)*
K212331

Device Name
BodySculp

Indications for Use *(Describe)*
The Bodysculp 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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510(K) Summary
BodySculp
K212331

This 510(K) Summary of safety and effectiveness for the BodySculp System is submitted in accordance with the requirements of 21 CFR 807.92 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Rohrer Aesthetics, LLC
Address:	Rohrer Aesthetics, LLC 105 Citation Court Birmingham, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	205-356-1172 – phone mrohrer@rohreraesthetics.com
Preparation Date:	November 9, 2021
Device Trade Name:	BodySculp
Product Code:	PKT
Regulation Number:	21 CFR 878.5400
Common Name:	Laser For Disruption Of Adipocyte Cells For Aesthetic Use
Legally Marketed Predicate Devices:	PowerSculp (Wuhan Lotuxs Technology Co, Ltd.)
Predicate 510(K) number:	K191068
Regulatory Class:	Class II Prescription Use
Description of the BodySculp System	The BodySculp is a diode laser system. The main components of BodySculp are a console and four applicators that deliver the laser energy to the patient. Electrically efficient semiconductors generate optical radiation (1060 nm) which issued to deliver laser energy to subcutaneous tissue layers.
Intended use of BodySculp System	The Bodysculp 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.

Results of Clinical Study: A human clinical study was not required as the device is identical to the predicate device.

Indications for Use Comparison:

Subject Device	Predicate Device	Comparison
The Bodysculp 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 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.	Identical

Technical Specifications Comparison:

Item	Proposed Device	Predicate Device	Comparison
Laser Type	Diode Laser	Diode Laser	Same
Wavelength	1060nm	1060 ± 20nm	Same
Lipolysis method	Heat-assisted	Heat-assisted	Same
Spot Size	4 × 8 cm^2 (A single applicator of four applicators)	4 × 8 cm^2 (A single applicator of four applicators)	Same
Peak Power	50W(per applicator)	50W (per applicator)	Same
Power Density	Up to 0.7-1.7W/ cm^2	Up to 0.7-1.7W/ cm^2	Same
Pulse Width	CW	CW	Same
Power Supply	AC100-240V/50-60Hz(customizable）	AC100-240V, 50/60Hz, 15A	Same
Peak Power	50W (per applicator)	50W (per applicator)	Same
Cooling	Contact Cooling	Contact Cooling	Same

Performance Data:

The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance

IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-22 Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment

Software Verification and Validation Testing for Moderate Level of Concern per FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices

An evaluation per ISO 10993-1 Evaluation of medical device – Part 1: Evaluation and testing within a risk management process was conducted. The evaluation determined that biocompatibility testing was not required because the materials and processes for the patient contacting material are identical to the predicate device and has been previously cleared by the FDA.

Conclusion:

The BodySculp laser lipolysis system is substantially equivalent to its predicate device with same indications for use and same technological characteristics. The non-clinical data for the BodySculp laser lipolysis system supports the safety of the device. There are no new concerns about safety or efficacy.