May 22, 2024

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

Re: K233099
Trade/Device Name: Gladiator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, OUH, GEX, IMG
Dated: April 19, 2024
Received: April 19, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.05.22 13:54:06 -04'00'

Long Chen, Ph.D.
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)*
K233099

Device Name
Gladiator

Indications for Use *(Describe)*
The Gladiator system contains three handpieces, each of which has its own indications for use.

The PiXel8-RF handpiece is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostatis.

The Bodysculp laser lipolysis handpiece 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 BodyTone handpiece is intended for Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increasing local blood circulation, Muscle re-education, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion. Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

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."

510(K) Summary
K233099

Applicant	Rohrer Aesthetics
Address	105 Citation Court Homewood, Alabama 35209
Contact Person	Mark Rohrer President, Rohrer Aesthetic
Contact Information	205-940-2200 mrohrer@rohreraesthetics.com
Preparation Date	May 22, 2024
Device Trade Name	Gladiator
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories Powered Laser Surgical System
Regulation Number	878.4400, 878.5400, 878,5860
Product Code	GEI, OUH, PKT, IMG
Regulatory Class	II
Legally Marketed Predicate Devices	Pinxel-RF system (K180654) BodySculpt (K212331) Futura Pro (K102524)

Device Description:
The Gladiator is a multi-function system that combines RF Microneedling, Low Level Laser and Electronic Muscle Stimulation (EMS) technologies into a single console. The system is intended for dermatologic and general surgery purpose as well as pain relief. The system is comprised of a single console with three handpieces:

- PiXel8-RF - a bipolar radiofrequency micro needling handpiece with disposable tips
- BodySculp – a low level laser
- BodyTone (previously called Futura Pro) – an electronic muscle stimulator

The system and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source.

Indications for use:

Each of the handpieces has its own indication for use.

The PiXel8-RF handpiece is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostatis.

510(K) Summary
K233099

The Bodysculp laser lipolysis handpiece 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 BodyTone handpiece is intended for Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increasing local blood circulation, Muscle re-education, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion. Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications for use comparison

Proposed Device RF Microneedling Handpiece	Pinxel-RF System K180654	Comparison
The RF Microneedling handpiece is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The RF Microneedling handpiece is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Same
Proposed Device BodySculp Handpiece	BodySculp K212331	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 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.	Same
Propose Device BodyTone Handpiece	Futura Pro K101524	Comparison
The BodyTone handpiece is intended for Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increasing local blood circulation, Muscle re-education, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion. Powered muscle stimulators should only be used under	The BodyTone handpiece is intended for Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increasing local blood circulation, Muscle re-education, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion. Powered muscle stimulators should only be used under	Same

medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.	medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.	

Technical Specifications Comparison

RF Handpiece

	Proposed Device Gladiator	**Predicate 1** PINXEL-RF system (K180654)	**Comparison**
System Type	Bipolar Radiofrequency	Bipolar Radiofrequency	Same
RF Frequency	4MHz	2MHz	Different. Thermal testing shows that the performance of the two devices is substantially equivalent.
Max Power	Max 25W @ 500ohm	Max 25W @ 500ohm	Same
Total Power delivered per treatment	25W	25W	Same
Power per pin	25W	25W	Same
RF Duration	50ms-950ms	50ms-950ms	Same
Tips	25, 49 and 64 pin microneedle electrodes	25 and 64 pin microneedle electrodes	Addition of one new electrode with 49 pins. The electrode is mid-way between the sizing of the others and does not impact the needle depth.
Needle Insert Depth	0.5-3.5mm	0.5-3.5mm	Same

BodySculp Handpiece

	Proposed Device BodySculp Handpiece	BodySculp K212331	Comparison
Laser Type	Diode Laser	Diode Laser	Same
Wavelength	1060nm	1060nm	Same
Lipolysis method	Heat-assisted	Heat-assisted	Same

510(K) Summary
K233099

	Proposed Device BodySculp Handpiece	BodySculp K212331	Comparison
Spot Size	4 × 8 cm2 (A single applicator of four applicators)	4 × 8 cm2 (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(customizable）	Same
Cooling	Contact Cooling	Contact Cooling	Same

Bodytone Handpiece

Item	**Description**	**Futura Pro (K102524)**	**Comparison**
Number of Output Modes	Two - Biphasic / Monophasic	Two - Biphasic / Monophasic	Same
Number of Output Channels	10 channels	10 channels	Same
Maximum RMS O/P Current	16.2 mA,m,@500 ohm	16.2 mA,m,@500 ohm	Same
Minimum electrode size	7.0 cm dia. (38.5 cm')	7.0 cm dia. (38.5 cm')	
Maximum Current Densitv IRMS\	0.421 mA/cm'@ 500 ohm	0.421 mA/cm'@ 500 ohm	Same
Maximum RMS Power Density	3.42 mW/cm' @ 500 ohm	3.42 mW/cm' @ 500 ohm	Same
pk current into 500 Ohms	120mA	120mA	Same
Max charge/Pulse	27.2 µC	27.2 µC	Same
pk voltage, no load	80 Volts	80 Volts	Same

Maximum frequency	100 Hz	100 Hz	Same
Max Pulse width	300 µs	300 µs	Same

Substantial Equivalence Discussion
The subject device, the Gladiator, is identical in indications for user and nearly identical in technical specifications to its predicate devices. The sole changes to the device functionality, the RF frequency and addition of one new RF microneedling tip do not have an impact on the safety or efficacy of the device. Thermal testing of the device at the new 4Mhz RF frequency shows that the change raises no new concerns of safety and efficacy.

Performance Testing
Verification and validation activities were successfully completed and establish that the Gladiator control unit performs as intended. Testing included the following:

- IEC 60601-1:2005 + Corr.1:2006 + A1:2012; Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-2:2014 + A1:2020; Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests;
- IEC 60601-2-2:2017; Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories;
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes;
- EN ISO 14971:2019+A11:2021; Medical Devices – Application Of Risk Management To Medical Devices

Thermal Testing
The following summarizes the thermal testing conducted to compare the new frequency of 4Mhz to the predicate's 2MHz frequency. Testing was conducted with 49-pin and 64-pin microneedling cartridges on three tissue types (*ex vivo* kidney, liver, and skin). Treatment settings included the three power levels: low (2.5 W), medium (7.5 W) and maximum (25 W), at a Pulse Width of 800 milliseconds (ms). Target penetration depth was 3.5 mm (e.g., max depth device delivers). Earlier generation PiXel8, operated on 2 MHz frequency, was used as the Predicate Device. The predicate was also equipped with the same microneedling cartridges as the Test Device and tested on all three types of tissue. Since the Predicate Device was used as a reference, it was tested for the worst cases only; e.g. maximum power level (25 W) and pulse width of 800 ms.

Thermal damage profiles for the Test and Predicate Devices were in close proximity in all test tissues. The Test Device showed somewhat milder thermal damage (moderately smaller CMZs) in treated tissues, which indicates a safer nature of the new generation PiXel8. At the same time, the study demonstrated the ability of the Test Device to achieve consistent thermal damage profiles in line with

the target treatment and were comparable to the profiles produced by the Predicate Device. Thus, it can be concluded that treatment by such a device at the appropriate testing settings will possess a desirable clinical treatment effect.

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Biocompatibility –

PiXel8 RF Microneedling handpiece

The only parts of the device in contact with the patient are the sterile needles of the microneedle tips. Per ISO 10993-1, the tips are classified as a limited duration external communicating device. The tip comes in contact with tissue / bone / dentin. The tips are constructed of stainless steel with gold plating and do not include any coloring. The plastic housing of the handpiece is made of a Polycarbonate resin. No new biocompatibility testing is required for this submission because the materials and the manufacturing process are identical to the original PinXel-8 device (K180654).

BodySculp

The patient contacting materials of Bodysculp are Sapphire Glass, gold plating, PET and polyester. As defined in Appendix A: ISO 10993-1:2009 these materials would be categorized as surface device contact with intact skin for limited duration. This categorization would require the minimal tests recommended by 10993-1. However, the materials and processing are identical to those used in the predicate device and other previously cleared medical devices, thus do not require additional testing.

No new biocompatibility testing is required for this submission because the materials and the manufacturing process are identical to the original BodySculp device (K212331).

Bodytone

The patient contacting materials of Bodytone handpiece is Silicone. As defined in Appendix A: ISO 10993-1:2009 these materials would be categorized as surface device contact with intact skin for limited duration. This categorization would require the minimal tests recommended by 10993-1. However, the materials and manufacturing processes are identical to those used in the predicate device. In addition, the FDA Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of

medical devices - Part 1: Evaluation and testing within a risk management process" lists silicone as exempt from testing if it is used on intact skin with limited contact.

Discussion

The subject device, the Gladiator, is identical in indications and nearly identical in technical specifications to its predicate devices. The sole changes to the device functionality, the RF frequency and addition of one new mid-sized RF microneedling tip do not have an impact on the safety or efficacy of the device.

The testing conducted and above comparison of devices shows that the Gladiator is substantially equivalent to the predicate devices.