February 2, 2024

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

Re: K233143
Trade/Device Name: PiXel8-Reveal
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, GEX, OUH
Dated: December 28, 2023
Received: December 28, 2023

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
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Tanisha Hithe
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)*
K233143

Device Name
Pixel8-Reveal

Indications for Use *(Describe)*
The PiXel8-Reveal contains two 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 Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

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
K233143
PiXel8-Reveal System

Applicant	Rohrer Aesthetics
Address	105 Citation Court Homewood, Alabama 35209
Contact Person	Mark Rohrer President, Rohrer Aesthetics
Contact Information	205-940-2200 mrohrer@rohreraesthetics.com
Preparation Date	January 24, 2024
Device Trade Name	PiXel8-Reveal
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories Powered Laser Surgical System
Regulation Number	878.4400, 878.4810
Product Code	GEI, OUH, GEX
Regulatory Class	II
Legally Marketed Predicate Devices	MultiLaser System(K123777) Pinxel-RF system (K180654)

Device Description:
The PiXel8-Reveal system is a multi-function laser and radiofrequency system intended for dermatologic and general surgery purposes. The system is comprised of a single console with two handpieces:

- PiXel8-RF - a bipolar radiofrequency microneedling handpiece with disposable tips
- Er:YAG - an Erbium:Yag single wavelength light-based handpiece.

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 indications for use.

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

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

510(K) Summary
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PiXel8-Reveal System

Indications for use comparison

RF Microneedling Handpiece		
Subject Device Indications	Predicate Device Indications	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
Er:YAG Handpiece		
Subject Device Indications	Predicate Device Indications	Comparison
The Erbium Yag (2940nm Wavelength) is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition, this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).	The Erbium Yag (2940nm Wavelength) is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition, this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).	Same. The Predicate device contains additional handpieces with their own indications, which are not listed here and not included in the PiXel8-Reveal

Technical Specifications Comparison

RF Handpiece

	Proposed Device PiXel8-Reveal	**Predicate 1** PINXEL-RF system (K180654)	**Reference Device**	**Comparison**
System Type	Bipolar Radiofrequency	Bipolar Radiofrequency	Bipolar Radiofrequency	Same
RF Frequency	4MHz	2MHz	4MHz	Different. Thermal testing shows that the performance of the two devices is substantially equivalent. Same as

510(K) Summary
K233143
PiXel8-Reveal System

	Proposed Device PiXel8-Reveal	**Predicate 1** PINXEL-RF system (K180654)	**Reference Device**	**Comparison**
				reference device.
Max Power	Max 25W @ 500ohm	Max 25W @ 500ohm	Max 25W@ 500 ohm	Same
Total Power delivered per treatment	25W	25W	25 W	Same
Power per pin	25W	25W	25W	Same
RF Duration	50ms-1000ms	50ms-950ms	50 ms – 950ms	Different. The difference is not large enough to impact safety or effectiveness
Tips	25, 49 and 64 pin microneedle electrodes	25 and 64 pin microneedle electrodes	25, 49 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. The 49-pin electrode is included in the reference device. The dimensions of the electrodes are the same.
Needle Insert Depth	0.5-3.5mm	0.5-3.5mm	0.5-3.5mm	Same

Er:YAG Handpiece

Specification	**Proposed Device** PiXel8-Reveal	**Predicate 2** K123777	**Comparison**
Wavelength	2940nm	2940 nm	same
Max Power	2.4W	2.4W	same
Max Fluence	Up to 10J/cm2	Up to 8J/cm2	Different. The difference is not large enough to impact the safety or effectiveness of the device.
Pulse Width	300 µs	300 µs	Same
Repetition Rate	Up to 5 pulses/second	Up to 10 pulses/second	Different.
Spot Size	1.5mm, 3mm, 6mm, 9mm	1.5mm, 3mm, 6mm, 9mm	Same

510(K) Summary
K233143
PiXel8-Reveal System

Substantial Equivalence Discussion

The subject device, the PiXel8-Reveal, 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 PiXel8-Reveal 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

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 – The only components of the device that come into contact with the patient are the needles in the microneedling disposable tips. The materials were deemed biocompatible with the clearance of K180654 and have not changed since that clearance.

Discussion

The subject device, the PiXel8-Reveal, 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 PiXel8-Reveal is substantially equivalent to its two predicate devices.