October 25, 2023

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

Re: K233147
Trade/Device Name: PiXel8-RF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, OUH
Dated: September 27, 2023
Received: September 27, 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.10.25 08:03:32 -04'00'

Mark Trumbore, 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)*
K233147

Device Name
PiXel8-RF

Indications for Use *(Describe)*

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

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.

510(K) Summary
PiXel8-RF System

This 510(K) Summary of safety and effectiveness for the PIXEL8-RF System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Rohrer Aesthetics
Address:	Rohrer Aesthetics 105 Citation Court Birmingham, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	205-356-1172 – phone mrohrer@rohreraesthetics.com
Preparation Date:	September 18, 2023
Type of Submission:	Special 510K
Device Trade Name:	Pixel8-RF System
Common Name:	Micro-Needle Fractional RF
Regulation Name:	Electrosurgical Cutting and Coagulation Device 79-GEI
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, OUH
LegallyMarketed Predicate Device(s):	Pixel8-RF (K180654)
Description of the PIXEL8-RF System:	The Pixel8-RF System includes the system main body, a bipolar handpiece with disposable micro-needle type electrodes, a footswitch and an LCD touch screen control panel. The RF Energy is delivered to a target tissue using a handpiece and disposable tip (micro needle electrode tip), the being placed in light contact with the tissue and the handpiece being held at right angles to the target tissue. As the RF energy passes through the tissue, it generates an electrothermal reaction which is capable of coagulating the tissue. The Pixel8 RF System

creates heat within the target tissue using micro-needles inserted from the tip.

Intended use of the PIXEL8-RF System	The PIXEL8-RF system is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostatis.
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 60601-2-2 Medical electrical equipment part 2: particular requirements for the basic safety and essential performance of high frequency surgical equipment In-Vivo testing was conducted on 3 types of tissue: Liver, Kidney and Muscle with results analyzed in a pathology lab. Results showed measurable thermal damage and no instances of unexpected injury.
Results of Clinical Study:	No clinical study was conducted to support this 510K submission.
Technical Specifications Comparison:	

	PiXel8 RF System (Subject Device)	Pinxel RF System (Predicate Device) K180654
Model	Pixel8 RF System	Pinxel RF System
Manufacturer	Rohrer Aesthetics	Rohrer Aesthetics
System Type	BiPolar RF	BiPolar RF
Output Energy Type	High Frequency	High Frequency
Frequency	4 MHz	2 MHz
Max Power	Max 25 W@ 500 ohm	Max 25 W @ 500 ohm
Total RF Treatment Level	Up to 20 (Max power 25 W)	Up to 20 (Max power 25W)
RF Duration	50 ms – 950ms	50ms – 950ms
Tips	MicroNeedle Electrodes 25, 49 and 64 pins	MicroNeedle Electrodes 25 and 64 pins
User interface	8” Touch LCD Display	Color touch LCD Display
System cooling	Air cooling	Air cooling
Dimensions (including Handpiece cable hanger	24 inches x 17 inches x 63 inches	24 inches x 17 inches x 63 inches)
Weight	8 lbs (without cart)	8 lbs (without cart)
Electrical rating	Single phase 110 - 230VAC, 60-60Hz Power consumption: 500VA (Fuse: 250V/6.3A)	Single phase 110 - 230VAC, 60-60Hz Power consumption: 500VA (Fuse: 250V/6.3A)

Conclusion:

The difference in the frequency does not raise new or different questions of safety or effectiveness. The performance data demonstrate that the subject device is as safe and effective as its predicate device for the intended use. Therefore, the PiXel8-RF system is substantially equivalent to its predicate device.