July 13, 2018

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

Re: K180654
Trade/Device Name: PINXEL-RF system
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, OUH
Dated: June 13, 2018
Received: June 14, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
510(K) Pending

Device Name

PINXEL-RF System

Indications for Use *(Describe)*

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

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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Attachment 5
510(K) Summary
PINXEL-RF System

This 510(K) Summary of safety and effectiveness for the PINXEL-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, 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:	February 17, 2018
Device Trade Name:	PINXEL-RF System
Common Name:	Micro-Needle Fractional RF
Regulation Name:	Electrosurgical Cutting and Coagulation Device & Acessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)
Legally Marketed Predicate Device: 510(K) number:	Secret RF Manufactured by ILOODA CO LTD. K170325
Regulatory Class:	Class II Prescription Use
Description of the PINXEL-RF System:	The PINXEL-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 tip 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 electro thermal reaction which is capable of coagulating the tissue. Using the micro needle tip, the PinXel system creates heat within the target tissue via micro- needles inserted from the tip.
Intended use of the PINXEL-RF System	The PINXEL-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 60501-1-2 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

ISO 11737-2 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

In-Vivo testing was conducted on 3 types of tissue: Liver Kidney and Muscle with results analyzed in a pathology lab. Results showed no instances of unexpected injury.

Technical Specifications Comparison:

	Proposed Device	Predicate Device
Model:	PinXel RF Device	Secret
Manufacturer:	Rohrer Aesthetics	ILOODA Co Ltd.
System Type	BiPolar RF	BiPolar RF
Output Energy type:	High Frequency	High Frequency
Frequency	2 MHz	2 MHz
Max.Power	Max 25 W @ 500 ohm	Max 25W @ 500 ohm
Total Power delivered per treatment	25W	25W
Power per pin	25W	25W
RF Duration	50ms-950ms	50ms-950ms
Tips	MicroNeedle Electrodes 25 and 64 pins	MicroNeedle Electrodes 25 and 64 pins
User interface	8” Touch LCD Display	Color touch LCD Display
Dimensions (including Handpiece cable hanger	24 inches x 17 inches x 63 inches	7.5 inches x 18.5inches x 43.5 inches (180(W) x 460(D) x 1100 (H))
Weight	8 lbs (without cart)	45 kg. (99 pounds)
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 treatment tip design does not raise new or different questions of safety or effectiveness. Furthermore, performance data demonstrate that the subject device is as safe and effective as its predicate device for requested intended use.
Therefore, PINXEL-RF System is substantially equivalent to its predicate device.