March 14, 2024

Aesthetic Management Partners
Shlomo Assa
Consultant
9019 Macon Road
Cordova, Tennessee 38016

Re: K232301
Trade/Device Name: Define RF Microneedling System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 2, 2024
Received: February 2, 2024

Dear Shlomo Assa:

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: 2024.03.14 10:07:29 -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)*

Device Name
DefineRF

Indications for Use *(Describe)*

DefineRF is indicated for use in dermatological 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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510(K) Summary
K232301
DefineRF

This 510(K) Summary of safety and effectiveness for the DefineRF 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	Aesthetic Management Partners
Address	9019 Macon Road Cordova, TN 38016
Contact Person	Shlomo Assa Consultant Acclaro Corporation
Contact Information	(619) 988-4796 sassa@acclaromd.com
Preparation Date	Februar 2, 2024
Device Trade Name	DefineRF
Classification Name	Electrosurgical cutting and coagulation
Common Name	RF Electrosurgical Device
Regulation Number	878.4400
Product Code	GEI
Regulatory Class	II
Legally Marketed Predicate Device	Agnes (K160469) Gowoonsesang Cosmetics Co., Ltd

Device Description:
DefineRF is a monopolar radiofrequency device that delivers up to 50W to the chosen location of the single needle tip. The device is equipped with a console with touchscreen user interface, a footswitch, a handpiece, a needle type RF electrode, and an FDA cleared single use neutral electrode pad (K092761). The needle tip is single use and provided sterile. The system is designed for use in a clinical environment for use on adults.

Indications for use:
DefineRF is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Device Comparison—Indications for Use:

Subject Device (DefineRF)	Predicate Device (Agnes K160469)	Reference Device (Darwin K212607, RF Microneedle only)	Comparison
DefineRF is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Agnes is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Darwin RF Microneedle handpiece is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Same

Device Comparison – Technical Specifications:

Specification	Define RF (Subject Device)	Agnes (K192728)	Reference Device (Darwin K212607, RF microneedle only)	Comparison
Product Code	GEI	GEI, KCW	GEI	The Define RF does not include the KCW product code because the device is not intended for epilation
Operation	The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.	The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.	The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.	Same
# of needles	1	1	10 and 25	Same
Frequency	1MHz	1MHz	2MHz	Same
Modality	Monopolar	Monopolar	Bipoloar	Same
Indications	DEFINE is indicated for use in dermatological and general surgical procedures for	AGNES is indicated for use in dermatological and general surgical procedures for	Use in dermatologic and general surgical procedures for electrocoagulation and	Same

	electrocoagulation and hemostasis.	electrocoagulation and hemostasis.	hemostasis	
Materials	Stainless steel with polyester based coating	Electrode: STS 304, Insulating Coating: pxylylene dimer C	Tip: Polycarbonate Needles: SU304	Different. The Define Rf has undergone biocompatibility testing to ensure safety of patient contacting materials
Power	50W	46W at 200Ω	Up to 36W	Different. The maximum power on the Define RF is slightly higher than the predicate device. However, performance testing shows their equivalence.
Return	Disposable neutral electrode pad	Disposable neutral electrode pad	N/A	Same
RF Duration	1-2000ms	50-2000ms	Not publicly available	Different. The minimum pulse duration on the Define is slightly lower than the predicate device. The difference is minimal and does not impact the safety or efficacy of the device.
Needle Length	Needle Length: 3.5mm (2.5mm active zone) Thickness: .37mm	Needle length : 0.8/1.25/1.5/ 2.0 mm Thickness : 0.2mm	0.5 – 3.5mm treatment depth	Different. The active zone of the Define RF needle is slightly longer than the predicate's longest needle, but the same as the reference device.
Single Use or Reusable	Single Use	Single use	Single Use	Same
Sterilization	EO gas	EO gas	EO Gas	Same
Max output voltage	160 V	104 V	Not publicly available	Different
Temperature	None	None	Not publicly available	Same

Sensors				
Impedance Monitor	Yes, during pulsing, the system continuously monitors impedance and adjusts output to deliver the selected power. As a safety feature, above 340Ω impedance, it faults and stops pulsing.	None	Not publicly available	Different. The Define RF has a more robust safety function than the predicate.
Continuity Monitor	There is no requirement for a grounding pad however the system will not operate without a grounding pad due to exceeding the maximum voltage.	Checking the connection between the neutral electrode and the electrosurgical unit.	Not publicly available	Different systems, but same level of safety function.
Electrode Monitor	Needles are monitored via RFID scanning	Provide a camera to monitor the electrode coating condition and shape before using by the user.	Not publicly available	Different systems. The Define RF system ensures that no needles are reused.
Output power levels	(3 to 20W) in 1 Watt increments	25 levels (2 to 46W)	10 levels (up to 36W)	While the max power outputs for the two devices are very similar, the Define RF has a functional output power level that is lower than the predicate. Functional testing (see details below) shows comparable performance between the two devices when tested to the 20W max output power.
Dimensions	368mm(W)x551mm(L)x607mm (H)	290mm(W)x455mm(L)x271.7 mm(H)	Unknown	Different
Weight	11.3kg	5.8kg	Not publicly available	Different
Power input	100-250VAC, 50-60Hz	100-250VAC, 50-60Hz	AC 220-240 V, 50 /60 Hz, 16A	Same

Footswitch Specifications	Single pole, double throw	Single pole, single throw	Not publicly available	Different. The double throw function of the Define predicate provides an additional layer of safety against misfiring from the footswitch.

Comparison

The DefineRF microneedling system is very similar to its predicate, the Agnes in its design, principle of operation and technical specifications and has the same indications for use. Both devices are single-need, monopolar radiofrequency systems with similar maximum output power, frequency, and pulse duration. The DefineRF contains additional safety features that are not present in the Agnes, including impedance regulation and needle scanning to ensure needles are not reused.

The needle length of the DefineRF is slightly longer than that of the predicate, however it is the same as the reference device's needle length. The Define RF thermal testing was conducted to a depth of 3.5mm. Thermal effect was evaluated through histopathology testing and the results show similar performance for the two devices and do not raise any problems in the safety and effectiveness.

Electrical Safety and Electromagnetic Compatibility

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards.

- IEC 60601-1: 2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2: 2017/AMD2:2020 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency.
- IEC 60601-1-2: 2014/AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Performance Testing - NonClinical

- ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Biocompatibility Tests were performed in accordance with FDA standards and all patient contacting materials were determined to be biocompatible.

- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
  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.
- EN ISO 14971:2019+A11:2021; Medical Devices – Application of Risk Management To Medical Devices

Sterility and Packaging

- ISO 11135: 2014, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11138-2: 2006, Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 11607-1: 2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-2:2019, Sterilization of medical devices - Microbiological methods -Part 2: Tests of sterility performed in the definition, validation and maintenance of sterilization process

Performance Testing

Testing was performed on three different tissue types recommended by the FDA: ex vivo kidney, muscle, and skin. Treatment setting included the three power levels, low (1.2J), medium (4.4.J) and maximum (6.8J), for skin and kidney specimens. For muscle specimen low (4 J), Medium (5.6), and maximum (8 J) power levels were tested. Treatments in all tissues were performed at the depths mimicking to dermis layer in all specimens. All treatments were performed at 37°C, the temperature close to physiological. Treatments produced clearly detectable Coagulation Micro Zones in all treated tissues at the target depths. Thermally damage profiles for the Test device were consistent in all test tissue. The study concluded that treatment by the device possessed a desirable clinical treatment effect.

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

Conclusion

510(K) Summary
K232301
DefineRF

The DefineRF microneedling system is very similar to its predicate, the Agnes in its design, principle of operation and technical specifications and has the same indications for use. Both devices are single-needle, monopolar radiofrequency systems with similar maximum output power, frequency, and pulse duration. The DefineRF contains additional safety features that are not present in the Agnes, including impedance regulation and needle scanning to ensure needles are not reused. The similarities in design and functionality as well as the results of histopathology testing shows that the DefineRF is substantially equivalent to the Agnes. In addition, testing and the additional safety features built into the DefineRF shows that the Define RF is as safe or safer than the predicate.