December 17, 2021

FCare Systems USA LLC
Patrick Danciu
President
11098 Biscayne BLVD, Suite 301
Miami, Florida 33161

Re: K210077
Trade/Device Name: MED RF4000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: ONQ
Dated: November 17, 2021
Received: November 19, 2021

Dear Patrick Danciu:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 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)*
K210077

Device Name
MED RF 4000

Indications for Use *(Describe)*
THE MED RF 4000 SYSTEM IS INTENDED FOR THE EPILATION AND FOR THE TREATMENT OF LOWER LIMB SPIDER VEIN OR TELANGECTASIA BY THERMOCOAGULATION.

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 K210077

SPONSOR	
Company Name	FCare Systems USA LLC
Company Address	11098 Biscayne Blvd Suite 301 Miami FL 33161
Telephone	786 288 0740
Contact Person	Patrick Danciu
Email	pdanciu@fcaresystems.us

Summary Prepared	December 16th 2021
Device name	MEDRF4000
Trade Name	MEDRF4000
Common Usual name	Electrosurgical Coagulation Device
Classification name	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code	ONQ
Device Class	Class II
Regulation number	21 CFR 878.4400

Predicate Device

Company	***Product***	***510(k)#***
FCare Systems NV	EVRF	K130283

Indications for Use

The MedRF4000 System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation

Device Description

The MedRF4000 consists of the following parts:

The generator: the generator creates the radiofrequency impulse and contains the software used to configure the impulse duration, impulse power and delay. Configuration of these settings is performed using the touchscreen.

The software of the generator displays the following information:

- Impulse width: The impulse width, also known as pulse length or pulse duration, can be set between 0.2s and 0.8s and changed in 0.1s increments.
- Power: The power can be set between 5% and 60% and can changed in 5% increments.
- Delay: The delay is the time between 2 pulses if the pedal is kept activated.
- Treatment timer: the treatment timer is started when the start button is pressed and stopped when the stop button is pressed. The timer is updated every second.
- Pulse counter: the pulse counter is updated each time the generator generates a pulse.
- Neutral electrode status: The screen shows the status of the conductive neutral electrode (pad) by means of the color of the Ω icon.
- Output connection: the screen shows the status of the output connection by means of the color of the A icon.

The combination of the power and impulse duration setting means that a highly accurate dose of energy can be delivered. The power and impulse values are accurately maintained by a microprocessor and displayed on a touch screen.

The generator is equipped with a contact quality monitor which is capable to detect the type of pad connected and, in case of a split pad, incorrect application. If the measured pad impedance is too high the device will automatically deactivate the output and go in safe mode. The contact quality is continuously monitored during treatment.

The pedal: The pedal is used to inform the generator when to send a pulse on the output. The pedal, made of hard plastic, is meant to be operated by foot in order to keep your hands free to perform the treatment.

The output cable: the output cable is used to connect the needle holder to the generator.

The neutral electrode cable (optional): The generator can be used with or without a neutral electrode connected to the patient. If a neutral electrode is used, then the neutral electrode cable needs to be used to make the connection between the neutral electrode and the generator.

The needle holder: The Ballet needle holder is used to hold the Ballet needle and transmits the pulse onto the tip of the needle. The needle holder has an easy press system to insert and

remove the ballet needle, making it possible to insert and remove the needle without touching it.

The following consumables can be used with the MedRF4000

The Ballet needles: The Ballet needle (Establishment Registration# 3005114964, as sterile, single-use, disposable needles and are device listed by Ballet as accessories to Needle-Type, High Frequency Epilators Product Code KCW) is used to deliver the radiofrequency pulse into the small spider vein. The needles are delivered sterile and are single use. The ultra-fine needle (Product Code KCW) has a diameter of 0.075 mm (K3i) or 0.15 mm (K6i) allowing for accurate operation and is protected by a specific isolating sheath. Needles are nickel. In case of a nickel allergy, gold needles are also available. The needles are disposable and can be used for a complete session.

The neutral electrode (optional): Optionally a conductive neutral electrode can be used, capacitive neutral electrodes cannot be used with the generator. The generator is compatible with the neutral electrode type 9160 of 3M Company.

Summary of Technological Characteristics

The MEDRF4000 method of action is the delivery of a controlled dose of high frequency energy to the vein, which stops the flow of blood to the area of concern. Once the flow of blood is interrupted, the appearance of the spider veins is greatly reduced or eliminated.

The power generator controls through a PC based controller board the delivery of stable energy to the needle and creates the impulse. The system utilizes a current of 4MHz. The impulse can be set between 0.1 seconds and 0.8 second in 0.1-second increments.

The power can be set between 5% and 60% in 5% increment for more precision in the treatment.

The casing of the unit has been redesigned for marketing and ergonomic purposes only using a touch color screen and a PC based controller board.

Software

The level of concern was determined to be moderate. The software information provided in this 510(k) followed the requirements found in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* Issued May 11, 2005.

Safety standards

The MEDRF4000 complies with the applicable requirements of:

- IEC 60601-1: 2006 /A11 2011 /A1 2013
- IEC 60601-2-2: 2018
- IEC 60601-1-2: 2014, group 1 Class A limits as per CISPR11 standard.

Substantial Equivalence Comparison Table

FEATURE	FCARE SYSTEMS Med RF 4000	FCARE SYSTEMS EVRF
510(k) Number	K210077	K083352
Classification and Product Code	878.4400 Product Code ONQ	878.4400 Product Code ONQ
Indications for Use	The MEDRF4000 System is intended for the epilation and for the treatment of lower limbs spider veins and telangectasia by thermocoagulation	The EVRF System is intended for the epilation and for the treatment of lower limbs spider veins and telangectasia by thermocoagulation
OTC or Rx	Rx	Rx
Mode of Action	Thermocoagulation of tissue by administration of high frequency energy	Thermocoagulation of tissue by administration of high frequency energy
Mode of Delivery	Disposable Epilation Needle	Disposable Epilation Needle
Disposable Epilation Needle	Ballet Technologies LTD	Ballet Technologies LTD
Modality	Monopolar	Monopolar
Frequency (Monopolar)	4 MHz (+/- 0.1 MHz)	4MHz-10 MHz (+/- 0.1 MHz)
Power Output-Monopolar balanced at 500 Ohms	25 watts	30 watts
Neutral electrode connection	Yes	No

As shown above, the MEDRF4000 is either within range or the same as the predicate device except that the MEDRF4000 has a neutral electrode connection, whereas the predicate device does not. To prove that the neutral electrode connection does not impose any safety risks, additional testing has been performed. The neutral electrode connection and its use in the MEDRF4000 is conform international standards, therefore SE to the predicate device has been proven.

Performance Testing

Comparison of the output signal of the EVRF and the MedRF40 was performed to determine if the output signal has the same effect when applied on pork tissue. The results indicate the EVRF (predicate device) and the MedRF4000 (subject device) with and without neutral electrode have equivalent effect,

Conclusion: The information discussed above demonstrates that the MEDRF4000 device is substantially equivalent to the predicate device, does not raise new issues of safety and effectiveness, and is as safe and effective as the predicate device as intended for use.