November 24, 2025

F Care Systems USA LLC
% Steven Mertens
Regulatory Affairs Manager
F Care Systems NV
Uitbreidingstraat 42-46
Berchem, Antwerpen 2600
Belgium

Re: K252704
Trade/Device Name: F Care RF System (00MEDRF4000US, 05RAFAELOPROBE, 05SPHERAPROBE, 06OUTPUTKAB, 06Pedal1St)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 5, 2025
Received: November 10, 2025

Dear Steven Mertens:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.11.24 14:45:37 -05'00'

For
Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252704

Please provide the device trade name(s).

F Care RF System (00MEDRF4000US, 05RAFAELOPROBE, 05SPHERAPROBE, 06OUTPUTKAB, 06Pedal1St)

Please provide your Indications for Use below.

F Care RF System is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures. The devices are prescription use (Rx) devices.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This 510(k) summary of safety and effectiveness is prepared in accordance with 21 CFR §807.92.

Date of preparation:	November 2, 2025
Applicant Information	Patrick Danciu President F Care Systems USA LLC 755 NE 164th Terrace Miami FL 33162
Phone:	+1 786 288 0740
E-mail:	pdanciu@fcaresystems.us
Legal Manufacturer:	F Care Systems NV Uitbreidingstraat 42-46 2600 Berchem, Belgium
Phone:	+32 3 451 51 45
Primary Correspondent:	Steven Mertens Regulatory Affairs Manager
E-mail:	steven.mertens@fcaresystems.com
Phone	+32 3 451 51 45

Device(s) Identification(s):

Device Trade Name:	F Care RF System
Common Name:	Radiofrequency Ablation System
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Indication for use	F Care RF System is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures. The devices are prescription use (Rx) devices.

Regulation Number	Product Code	Device Class
878.4400	GEI	Class II

Table 1: Device Identification

Legally Marketed Equivalent Device(s):

510(K) Number	Device Name	Manufacturer
K220725	HPR45i (Primary predicate device)	F Care Systems NV
K210077	Med RF 4000	F Care Systems NV

Table 2: Predicate Device

F Care RF System design

F Care RF System is designed for thermocoagulation (RF) of tissue by administration of high frequency energy by means of electrosurgical electrodes of soft tissue in a broad range of surgical procedures. The system consists of:

- MedRF4000, electrosurgical generator (00MEDRF4000US)
- Rafaelo probe, electrosurgical electrode (05RAFAELORPROBE)
- Sphera probe, electrosurgical electrode (05SPHERAPROBE)
- Output cable (06OUTPUTKAB)
- Foot pedal (06PedalST1)

The F Care RF System includes the MedRF4000 generator and two sterile, single-use monopolar electrodes. the Rafaelo and Sphera probes designed to deliver high-frequency radiofrequency (RF) energy to soft tissue for coagulation and hemostasis. The system is for prescription use only and intended for trained healthcare professionals.
The MedRF4000 generator, previously cleared under 510(k) K210077, has been modified to remove the USB interface; no other changes have been made to its performance or design. The Rafaelo probe connects directly to the generator, while the Sphera probe connects via a reusable handle. Only one probe is used per procedure. The Rafaelo probe consists of a handle, output cable, and a stainless-steel tube with a sharp, insulated tip. The Sphera probe includes a handle and a rounded, ball-shaped insulated tip. Both feature anti-adhesive coated tips and are intended for external communication with limited (<24-hour) contact duration.
Radiofrequency energy from the generator is delivered through the probe tip and converted into heat in the tissue, causing coagulation. Visual and audible signals from the MedRF4000, including beeps every 2 seconds and energy alerts at 500 J and 1500 J, help track treatment. If these indicators fail, treatment must be stopped to avoid thermal injury.

The Rafaelo and Sphera probes are substantially equivalent to the predicate device HPR45i in design, function, materials, and intended use. Both subject and predicate devices use similar

biocompatible materials, are activated via foot pedal, and are EO-sterilized under the same sterilization cycle. They do not have power regulation or diagnostic features.Functionally, the Rafaelo probe is used internally with a sharp tip, while the Sphera probe is used externally with a rounded tip. The Rafaelo probe is packaged in a double sterile pouch, and the Sphera probe in a single sterile pouch. Overall, the F Care RF System, including the updated MedRF4000 and both probes, is safe, effective, and substantially equivalent to the predicate device for soft tissue coagulation in surgical procedures.

Table 1: Substantial Equivalence Comparison

Characteristic / Feature	**F Care RF System (subject device)**	**HPR45i (Primary predicate device)**	**Med RF 4000 (Secondary predicate device)**	**Comments**
Device Name	F Care RF System	HPR45i electrode	Med RF 4000	N/A
Manufacturer Name	F Care Systems NV	F Care Systems NV	F Care Systems NV	Same
510(K) Number	To be assigned by the FDA	K220725	K210077	N/A
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Same
Product code	GEI	GEI	ONQ	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Class	Class II	Class II	Class II	Same
Intended Use/ Indications for Use	The F Care RF System is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures. The device is a	HPR45i electrosurgical electrode is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a	The MEDRF4000 System is intended for the epilation and for the treatment of lower limbs spider veins and telangectasia by thermocoagulation	Refer to **Justification 1**

Characteristic / Feature	F Care RF System (subject device)	HPR45i (Primary predicate device)	Med RF 4000 (Secondary predicate device)	Comments
	prescription use (Rx) device.	broad range of surgical procedures. The device is a prescription use (Rx) device.		
Mode of Action	Thermocoagulation (RF) of tissue by administration of high frequency energy	Thermocoagulation (RF) of tissue by administration of high frequency energy	Thermocoagulation (RF) of tissue by administration of high frequency energy	Same
Components	Electrosurgical Generator was approved along with the neutral electrode, active electrode, foot pedal,	Electrosurgical Generator was approved along with the neutral electrode, active electrode, foot pedal,	/	Same
Output Energy type	Radio Frequency	Radio Frequency	Radio Frequency	Same
Frequency	4 MHz	4 MHz	4 MHz	Same
Maximum power	25W	25W	25W	Same
Compatible generator	MedRF4000	MedRF4000	/	Same, the only difference is the removal of the USB interface in the to-be-marketed device.
Mode of delivery	Disposable Electrode	Disposable Electrode	Disposable Electrode	Same
Modality	Monopolar	Monopolar	Monopolar	Same

Characteristic / Feature	F Care RF System (subject device)	HPR45i (Primary predicate device)	Med RF 4000 (Secondary predicate device)	Comments
Rx or OTC	Prescription Use	Prescription Use	Prescription Use	Same
Electrode Material	Stainless steel AISI304L	Stainless steel AISI316L	/	Similar. Refer to **Justification 2**
Shape of electrode tip	Sharp Or round	Sharp	/	Different. Refer to **Justification 3**
Length of the electrode tip	3 mm (05SPHERAPROBE) 10 mm (05RAFAELOPROBE	10 mm	/	Different for Sphera probe. Refer to **Justification 4**
Electrode length from tip to handle	182 mm (05SPHERAPROBE) 155 mm (05RAFAELOPROBE)	143 mm	/	Similar. Refer to **Justification 5**
Electrode tip coating	Yes, CrN	No	/	Refer to **Justification 6**
Electrode insulation Material	PFA	PTFE	/	Similar. Refer to **Justification 7**
Patient Contacting Material	AISI304L, PFA and CrN	AISI316L and PTFE	/	Similar: Refer to **Justification 2,6 and 7.**
Sterilization	EO	EO	/	Same
Single Use	Yes	Yes	/	Same
Shelf life of the	3 years	3 years	/	Same

Characteristic / Feature	F Care RF System (subject device)	HPR45i (Primary predicate device)	Med RF 4000 (Secondary predicate device)	Comments
electrode				

Justification 1:
The difference lies solely in the indications for use; the intended use, coagulation or thermocoagulation, remains the same throughout, and the technological characteristics are the same. Both the subject and predicate devices are not standalone devices and require each other to achieve their intended use; therefore, it was decided to register the products as a system. The HPR45i device, cleared under FDA 510(k) number K22075, underwent safety and performance testing in conjunction with the Med RF 4000 (K210077), which is now part of the F Care RF System submission and was also used in its safety and performance evaluations. HPR45i serves as the primary predicate device, as the only changes in the F Care RF System are the introduction of two new electrosurgical electrodes: the Rafaelo probe (05RAFAELOPROBE) and the Sphera probe (05SPHERAPROBE). These have proven substantially equivalence in safety and performance to the primary predicate device (HPR45i) and the secondary predicate device (Med RF 4000) where the only change compared to the previously marketed device is the removal of the USB interface.

Justification 2: Stainless steel type 304L was used instead of 316L due to the fact that 316L contains molybdenum which is corrosion resistant and is not needed since the probes are only used for a short period of time (approx. 5 min.). The minor difference in subtype of stainless steel wil not affect the safety and performance of the probes which has been demonstrated by a biocompatibility report (safety) and ex-vivo tissue test reports (performance).

Justification 3, 4 and 5: The different shape of tip and length of probe were chosen to provide the physician with a different option for ablation. The ex-vivo test reports show that the ablation of the Sphera probe is equivalent to the HPR45i. Therefore we can conclude that this difference does not raise any concern on the safety and effectiveness of the Sphera probe.

Justification 6: The antiadhesive Chromium Nitride (CrN) coating on the tip was added to prevent the coagulated tissue debris from adhering to the tip of the probe. The CrN coating will not affect the safety and performance of the probes which has been demonstrated by a biocompatibility report(safety) and ex-vivo tissue test report (performance).

Justification 7: PFA was used instead of PTFE due to PFA having a lower shrinking temperature which facilitates the production process. The difference in subgroup of polymers will not affect the safety and performance of the probes which has been demonstrated by biocompatibility testing (safety) and ex-vivo tissue test reports (performance).

Summary of Non- Clinical Data

The non-clinical performance tests have been executed in line with recommendations of the

FDA guidance: "**Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.** The following performance tests were carried out for the system.

Biocompatibility

The Rafaelo probe and Sphera probe are externally communicating devices with limited duration (<24hrs) of contact with tissue and blood as per ISO 10993-1. Endpoints that were considered were: cytotoxicity, sensitization, irritation and acute systemic & pyrogenicity. Test results confirmed that the devices have met the requirements set in ISO 10993-1 and "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" .

Thermal Effects Testing

An ex-vivo study was conducted using a porcine model to evaluate the technical success into three soft tissues of the Rafaelo probe and Sphera probe compared to the HPR45i (predicate device K220725). The results confirmed the substantial equivalent thermal behaviour of the Rafaelo probe and Sphera probe and presented the same efficacy and technical success rate as the predicate device.

Electrical Testing

Electrical verification testing was conducted the to ensure compliance with current electrical standard requirements. (IEC 60601-1, IEC 60601-2-2)

Electromagnetic compatibility

Electromagnetic compatibility (EMC) testing has been completed for the applicable parts of the F Care RF System. The results demonstrated compliance of the proposed system to current IEC 60601-1-2 standard requirements.

Software verification and validation

Software for the MedRF4000 was developed and verified and validated according to the current version of IEC 62304 and FDA Guidance 'Content of Premarket Submissions for Device Software Functions'.

Summary of Clinical Data

As per FDA's guidance document, **"Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"** Clinical data are generally not necessary to support 510(k) submissions for electrosurgical devices that are intended for general surgery indications. Moreover, indications for use, device technology and mechanism of action of the is identical when compared to the predicate device. Therefore, no clinical data was submitted for the subjected devices.

Conclusion

Based on the comparison and analysis above, the proposed system "F Care RF System" is determined to be Substantially Equivalent (SE) to the predicate devices "HPR45i"

Electrosurgical Electrode and “Med RF 400” electrosurgical generator.