June 2, 2026

F Care Systems USA, LLC
% Steven Mertens
Official Correspondent
F Care Systems NV
Uitbreidingstraat 42-46
Berchem, Antwerp 2600
Belgium

Re: K253918
Trade/Device Name: Veineo System (00MEDRF4000TCUS 05CR45iT 06Pedal1St)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 5, 2026
Received: May 7, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.02 17:01:52 -04'00'

Colin K. 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.	K253918

Please provide the device trade name(s).

Veineo System (00MEDRF4000TCUS
05CR45iT
06Pedal1St)

Please provide your Indications for Use below.

The Veineo System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux. The devices are prescription use (Rx) devices.

Please select the types of uses (select one or both, as applicable).	☒ 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: June 1th , 2026

Applicant Information	F Care Systems NV Uitbreidingstraat 42-46 2600 Berchem, Belgium
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 Identification:

Device Trade Name:	Veineo system
Common Name:	Radiofrequency Ablation System
Classification Name:	Electrosurgical cutting and coagulation device and accessories

Regulation Number	Product Code	Device Class
878.4400	GEI	Class II

Table 1: Device Identification

Legally Marketed Equivalent Device:

510(K) Number	Device Name	Manufacturer
K111887	CLOSUREFAST RADIOFREQUENCY CATHETER	COVIDIEN
K141858	ClosureRFG Radiofrequency Generator	COVIDIEN

Table 2: Predicate Device

Device Description

The Veineo system is designed for endovascular coagulation of blood vessels in patients with superficial vein reflux. The device is a prescription use device which is intended to be used by a healthcare professional trained on device's intended use in a professional healthcare environment. The system consists of:

- MedRF4000, electrosurgical generator (00MEDRF4000TCUS)
- CR45iT, endovascular catheter (05CR45iT)
- Neutral electrode cable (06KAB3M)
- Foot pedal (06PedalST1)

The CR45iT is an endovascular catheter which can be inserted into the varicose vein using a 6F introducer as accessory. The CR45iT catheter is supplied sterile (sterilized by EO Sterilization) and is not intended to be reused.

The CR45iT catheter consists of 4 different parts such as the tip, the stainless-steel tube, thermocouple and output cable. The stainless-steel tube is insulated over most of its exposed

length, and it is connected to the stainless steel tip at the end which has an anti-adhesive coating. The stainless-steel tube is covered by insulation which makes that the tip and insulation are the direct patient contacting parts of the CR45iT catheter. The CR45iT is an externally communicating medical device that comes into contact with circulating blood for a limited contact duration (≤24h).

The generator can be operated using the touchscreen. Output activation is controlled using a pedal requiring continuous activation. Deactivation of the pedal will immediately deactivate the output and as a result the heating of the vein will stop. Visual and audible signals from the MedRF4000 assist the user with the segmental pullback and warnings. If these indicators fail, treatment must be stopped to avoid thermal injury. The MedRF4000 requires a neutral electrode to be placed on the patients body to act as an energy return pathway. The MedRF4000 has a contact quality monitoring system and is compatible with split neutral electrodes.

The associated accessories include:

- 6F introducer
- Neutral electrode

Intended Use/Indications for Use

The Veineo System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux. The devices are prescription use (Rx) devices.

Indications for Use Comparison

Intended use of the subjected and predicate device are same, as both are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Substantial equivalence table:

	ClosureFast Radiofrequency Catheter (predicate device)	**CLOSURERFG RADIOFREQUENCY GENERATOR (Secondary predicate device)**	**Veineo System (Subject device)**
Device Name	ClosureFast Radiofrequency Catheter	CLOSURERFG RADIOFREQUENCY GENERATOR	Veineo System
Manufacturer Name	Medtronic, Inc.	Covidien	F Care Systems NV
510(K) Number	K111887	K141858	To be assigned by the FDA

	ClosureFast Radiofrequency Catheter (predicate device)	CLOSURERFG RADIOFREQUENCY GENERATOR (Secondary predicate device)	Veineo System (Subject device)
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Product code	GEI	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Class	Class II	Class II	Class II
Indications for Use	The ClosureFast catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.	The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.	The CR45iT catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.
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
Output Energy type	Radio Frequency	Radio Frequency	Radio Frequency
Disposable/Single-use Device	The RF catheters are disposable and are to be used within a single patient procedure only.	/	The RF catheters are disposable and are to be used within a single patient procedure only.
Sterilization Method	EO	/	EO
Modality	Bipolar	Bipolar	Monopolar
Rx or OTC	Prescription Use	Prescription Use	Prescription Use
Introducer sheath compatibility	7F	/	6F

	ClosureFast Radiofrequency Catheter (predicate device)	CLOSURERFG RADIOFREQUENCY GENERATOR (Secondary predicate device)	Veineo System (Subject device)
Outer diameter of catheter	7F	/	6F
Heating element diameter	2.3 mm	/	2.0 mm
Catheter length	700 mm	/	700 mm
Pull back marking	Yes	/	Yes
Pull back markings distance	65 mm	/	6 mm
Insertable length	600 mm	/	600 mm
Heating element length	70 mm	/	5.0 mm
Connector type	6 pin	6 pin	7 pin
Max. power setting	40W (at 200 ohms)	40W (at 200 ohms)	29W (at 1000 Ohms)
Default target temp. setting	120 °C	120 °C	120 °C
Working temperature	120 °C	120 °C	90 – 120 °C
Temperature measurement	Thermocouple	Thermocouple	Thermocouple.
Read out frequency of temperature	/	Unknown	Every 300 ms by the generator
Voltage Supply generator	/	100-240VAC 50 - 60 Hz	100-240VAC 50 - 60 Hz
Output frequency generator	480 kHz	480 kHz	4 MHz
Continuity monitor	/	Yes	Yes
Crest factor	/	1.4	1.4
Working mode	Coagulation	Coagulation	Coagulation
Tip coating	FEP	/	Stainless steel with CrN
Patient contacting	PET, FEP, PEEK	/	PTFE

	ClosureFast Radiofrequency Catheter (predicate device)	CLOSURERFG RADIOFREQUENCY GENERATOR (Secondary predicate device)	Veineo System (Subject device)
materials			

Technological Comparison

The mechanism of action of both devices is endovascular coagulation of blood vessels by administration of high frequency energy. The subjected and predicate device are intended to carry the energy provided by the generator to target blood vessels in patients with superficial vein reflux. Both the CR45iT (subject) and ClosureFast Radiofrequency Catheter (predicate device) consists of pullback markings, have similar catheter lengths and diameter of heating element. They both have a temperature measurement function by thermocouple which continuously measures the temperature in the blood vessel. The patient contacting materials of the CR45iT are similar for the subject and predicate device and is confirmed to be safe and efficient by biocompatibility and in-vivo tissue testing. The subject and predicate device are supplied sterile and sterilized using EO sterilization. Therefore, it is evident that, the subjected and predicate device have equivalent technological characteristics. Based on the technological specification comparison and justifications of the differences provided in the submission, the subject (CR45iT) is determined to be substantially equivalent to the ClosureFast Radiofrequency Catheter (predicate device) in terms of mode of action, intended use, principle of operation, function, and technological characteristics.

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 CR45iT:

Biocompatibility

The CR45iT is an externally communicating medical device that comes in contact with circulating blood for a limited contact duration (≤24h). as per ISO 10993-1. Endpoints that were considered were: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity, hemocompatibility and chemical characterization. Test results confirmed that the device has 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

A side-by-side study assessing thermal effects compared performance of the CR45iT to

the predicate device. The results confirmed substantial equivalence of the CR45iT compared to 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'.

Conclusion

Based on the comparison and analysis above, the proposed device "Veineo system" is determined to be Substantially Equivalent (SE) to the predicate device, ClosureFast Radiofrequency Catheter & ClosureRFG Radiofrequency Generator.