July 24, 2026

Fresenius Medical Care Renal Therapies Group, LLC
c/o Timothy Groves
Regulatory Affairs - Senior Lead
920 Winter St.
Waltham, Massachusetts 02451

Re: K261267
Trade/Device Name: Careflux H60; Careflux H70; Careflux V500
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: June 23, 2026
Received: June 23, 2026

Dear Timothy Groves:

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,

Gema Gonzalez -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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.	K261267

Please provide the device trade name(s).

Careflux H60;
Careflux H70;
Careflux V500

Please provide your Indications for Use below.

Careflux H60 and H70
The careflux dialyzers are intended for single use only for extracorporeal blood purification during the intermittent kidney replacement therapies hemodialysis (HD) and isolated ultrafiltration for patients suffering from kidney disease.

Careflux V500
The careflux dialyzers are intended for single use only for extracorporeal blood purification during the intermittent kidney replacement therapies hemodialysis (HD) and hemodiafiltration (HDF) using pre-, post-, or mixed dilution modes, and isolated ultrafiltration for patients suffering from kidney disease.

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

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

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 460-1087
Fax:	(781) 699-9635
Contact Person:	Timothy Groves, Senior Lead
Preparation Date:	16 April 2026

1.2. Device Name

Trade Name:	Careflux H60; Careflux H70; Careflux V500
Common Name:	Dialyzer
Regulation Name:	High Permeability hemodialysis system
Regulatory Class:	Class II per 21 CFR § 876.5860
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System
FDA Review Panel:	Gastroenterology/Urology

1.3. Legally Marketed Predicate Device

The legally marketed primary predicate devices are the FX CorAL 60, 80, 100, 120, 600, 800, and 1000 Dialyzers cleared under K243874. The secondary predicate devices are the Optiflux dialyzers cleared under K162488. The Polyflux 140H dialyzer (K043342) is being used as a reference device. The predicate devices have not been subject to design-related recalls.

1.4. Device Description

1.4.1. Device Identification

The Careflux H60; Careflux H70; Careflux V500 dialyzers are the subject of this 510(k) and are available in three (3) configurations as shown in Table 1.

Table 1: Careflux H60; Careflux H70; Careflux V500 Dialyzers

Trade Name	Product Number	Surface Area (m^2)
Careflux H60	F00012687	1.4
Careflux H70	F00012688	1.6

Trade Name	Product Number	Surface Area (m^2)
Careflux V500	F00014020	1.3

1.4.2. Device Characteristics

The Careflux H60; Careflux H70; Careflux V500 dialyzers are high-flux, single-use, steam-sterilized hemodialyzers. The dialyzers are provided blood pathway sterile and non-pyrogenic. The dialyzers allow for the transfer of water and solutes between blood and dialysate using semipermeable, hollow fiber membranes.

1.4.3. Environment of Use

The Careflux H60; Careflux H70; Careflux V500 dialyzers are used in environments where acute and chronic hemodialysis are performed.

1.4.4. Brief Written Description of the Device

The Careflux H60; Careflux H70; Careflux V500 dialyzers are high-flux, sterile devices designed for single-use acute and chronic hemodialysis. The dialyzers are configured to connect to a bloodline set which connects to a patient's vascular access system when used with a hemodialysis machine equipped with ultrafiltration control. During treatment, blood is pumped from the patient's body through an extracorporeal circuit, one component of which is the dialyzer. The dialyzers contain a semi-permeable membrane that allows for diffusion and/or convection to transport toxins and excess fluid from the blood compartment (fiber lumen) to the dialysate or filtrate compartment. Dialyzers utilize a counter-current flow in which dialysate and blood flow in opposite directions in the dialyzer during hemodialysis. The counter-current flow maintains the concentration gradient across the membrane for waste and fluid removal.

1.4.5. Materials of Use

The Careflux H60; Careflux H70; Careflux V500 dialyzers are classified as external communicating devices having direct contact via circulating blood and chronic long-term use exposure (> 30 days, Classification C), Class II devices in accordance with FDA guidance *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (08 September 2023).

The Careflux H60; Careflux H70; Careflux V500 dialyzers' components are composed of the following materials:

Component	Material
Housing	Polypropylene
Potting Resin	Polyurethane
Fiber Bundle	Polysulfone-polyvinylpyrrolidone blend, α-tocopherol (vitamin E)
Flange	Polypropylene
Blood Port Cap(s)	Polypropylene, Silicone
Dialysate Port Cap(s)	Styrol-Ethylen-Butylen-Styrol, Polypropylene

1.4.6. Key Performance Specifications/Characteristics

Urea clearance is a key performance specification of the Careflux H60; Careflux H70; Careflux V500 dialyzers. FMCRTG uses sodium clearance as a marker for urea clearance because sodium and urea exhibit similar movement across the membrane. Urea clearance data from the Instructions for Use (IFU) is provided in Table 2, where Qb = blood flow rate, Qd = dialysate flow rate, and Qf = filtration flow rate. The Qf is equal to the ultrafiltration rate (Quf) plus the substitution flow rate (Qs), where Qs = 0 in hemodialysis.

Table 2: *In vitro* Urea Clearance for the Careflux H60; Careflux H70; Careflux V500 Dialyzers

Trade Name	Flow Rate Conditions (mL/min)			Typical Urea Clearance (mL/min)
	Qb	Qd	Qf	
Careflux H60	300	500	0	272
Careflux H70	300	500	0	278
Careflux V500	300	500	75	279

1.5. Intended Use

Removal of uremic toxins including excess water and correction of blood electrolytes and acid-base balance in an extracorporeal treatment.

1.6. Indications for Use

1.6.1. Careflux H60 and H70 Dialyzers

The careflux dialyzers are intended for single use only for extracorporeal blood purification during the intermittent kidney replacement therapy hemodialysis (HD) and isolated ultrafiltration for patients suffering from kidney disease.

1.6.2. Careflux V500 Dialyzer

The careflux dialyzers are intended for single use only for extracorporeal blood purification during the intermittent kidney replacement therapies hemodialysis (HD) and hemodiafiltration (HDF) using pre-, post-, or mixed-dilution modes, and isolated ultrafiltration for patients suffering from kidney disease.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the proposed Careflux H60; Careflux H70; Careflux V500 dialyzers are equivalent to the predicate FX CorAL dialyzers (K243874) and secondary predicate Optiflux dialyzers (K162488):

- Intended Use and Indications for Use
- Principle of Operation
- Design and Configuration

- Technological Characteristics
- Materials
- Performance Requirements

1.8. Performance Data

Performance testing was conducted in accordance with ISO 8637-1 First Edition 2017-11 and *Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers, August 1998*. Testing conducted to support the determination of substantial equivalence is summarized in Table 3.

Table 3: Performance Testing Summary

Test Conducted	Test Method Description
Blood Compartment Volume	Calculated using the fiber volume and CAD software modeling for the flange volume. Results were compared with the acceptance criteria.
Clearance – Sodium (marker for urea), Creatinine, Phosphate, Vitamin B_{12}, Cytochrome C	Calculated by analyzing test samples over the specified range of blood, dialysate, and filtration flow rates
Protein Sieving Coefficient	The test circuit was stabilized for blood and filtrate flows. All air was removed from the dialyzer. Paired samples for blood and filtrate flows were collected after 30 min. The sieving coefficient was calculated in accordance with ISO 8637-1 First Edition 2017-11
Ultrafiltration (Blood K_{uf})	Calculated as the slope from a plot of the measured ultrafiltration rate (UFR) over the applied transmembrane pressure (TMP) range versus the applied TMP
Pressure Drop	Blood compartment: The blood compartment was perfused with human blood while the dialysate compartment was filled with NaCl solution Dialysate side: Both compartments were filled with dialysis fluid. Inlet and outlet pressures of the blood and dialysate compartments were measured across the range of flow rates with the dialyzers in a horizontal position.
Structural Integrity (Dialyzer Integrity)	The positive and negative pressure decay was measured by a pressure monitor connected at one end of the dialyzer after applying 4.5 bar and -700 mmHg from the opposite ends and equilibrium was reached
Blood Compartment Integrity (Membrane Integrity)	Water was added to the dialyzer. A pressure differential was applied across the dialyzer membrane via pressurized air. The outlet blood port of the dialyzer was observed for air bubbles.
Simulated Shipping and Distribution	Testing was conducted per ASTM D4169-22. Performance testing was conducted after simulated shipping and accelerated aging to demonstrate that product and package integrity, and sterility are maintained throughout the intended product's shelf life.

All testing met predetermined acceptance criteria and demonstrated that, like the predicate devices, the Careflux H60; Careflux H70; Careflux V500 dialyzers are safe and effective for their intended use.

1.8.1. Biocompatibility Testing

Testing was performed to support the biological safety of the Careflux H60; Careflux H70; Careflux V500 dialyzers:

- Chemical Analysis – Extractables and Leachables
  - Targeted Quantitative Analyses
- Cytotoxicity, ISO Neutral Red Uptake
- Sensitization, ISO Guinea Pig Maximization
- ISO Intracutaneous Irritation
- ISO Acute Systemic Toxicity
- ISO Subchronic Toxicity, Short-Term (14-Day) Repeated Exposure
- Material-Mediated Pyrogenicity
- Genotoxicity, ISO Bacterial Reverse Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Hemocompatibility, ASTM Hemolysis (Direct and Indirect – Extract)
- Hemocompatibility, Complement Activation – SC5b-9 fragment
- Hemocompatibility, ASTM Partial Thromboplastin Time
- Hemocompatibility, Platelet and Leukocyte Counts
- Hemocompatibility, Mechanical Hemolysis
- Hemocompatibility, *in vitro* Thrombogenicity Assay

A toxicological risk assessment was also performed.

1.8.2. Human Factors Validation Testing

The Careflux H60; Careflux H70; Careflux V500 dialyzers were validated for safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Careflux H60; Careflux H70; Careflux V500 dialyzers are not electrical mechanical devices.

1.8.4. Software Verification and Validation Testing

Not applicable. The Careflux H60; Careflux H70; Careflux V500 dialyzers do not contain software.

1.8.5. Animal Studies

No animal studies were performed.

1.8.6. Clinical Studies

No clinical studies were performed.

1.9. Conclusion

The intended use, indications for use, principle of operation, technological characteristics, design, materials, and performance requirements are substantially equivalent to those of the predicate and secondary predicate devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Careflux H60; Careflux H70; Careflux V500 dialyzers are safe and effective for their intended use.