February 28, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Timothy Groves
Regulatory Affairs - Senior Lead
920 Winter Street
Waltham, Massachusetts 02451

Re: K243874
Trade/Device Name: FX CorAL 60 (F00012969); FX CorAL 80 (F00012970); FX CorAL 100 (F00012971); FX CorAL 120 (F00012972); FX CorAL 600 (F00012973); FX CorAL 800 (F00012974); FX CorAL 1000 (F00012975)
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: December 17, 2024
Received: December 17, 2024

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 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,

Maura Rooney -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243874

Device Name
FX CorAL 60 (F00012969); FX CorAL 80 (F00012970); FX CorAL 100 (F00012971); FX CorAL 120 (F00012972); FX CorAL 600 (F00012973); FX CorAL 800 (F00012974); FX CorAL 1000 (F00012975)

Indications for Use *(Describe)*
The FX CorAL hemodialyzers are intended for single use only for extracorporeal blood purification during intermittent renal replacement therapies hemodialysis (HD), hemodiafiltration (HDF) using pre-, post or mixed-dilution modes, and isolated ultrafiltration for patients suffering from renal insufficiency.

The FX CorAL hemodiafilters are intended for single use only for extracorporeal blood purification during intermittent renal replacement therapies hemodialysis (HD), hemodiafiltration (HDF) using pre-, post or mixed-dilution modes, and isolated ultrafiltration for patients suffering from renal insufficiency.

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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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:	17 December 2024

1.2. Device Name

Trade Name:	FX CorAL
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 K220721. The predicate has not been subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

The FX CorAL dialyzers are the subject of this 510(k) and are available in seven (7) configurations as shown in Table 1.

Table 1: FX CorAL Dialyzers

Trade Name	Product Number	Surface Area (m^2)
FX CorAL 60	F00012969	1.4
FX CorAL 80	F00012970	1.8
FX CorAL 100	F00012971	2.2

Table 1: FX CorAL Dialyzers

Trade Name	Product Number	Surface Area (m^2)
FX CorAL 120	F00012972	2.5
FX CorAL 600	F00012973	1.6
FX CorAL 800	F00012974	2.0
FX CorAL 1000	F00012975	2.3

1.4.2. Device Characteristics

The FX CorAL 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 FX CorAL dialyzers are used in environments where acute and chronic hemodialysis are performed.

1.4.4. Brief Written Description of the Device

The FX CorAL 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 hemodialysis, blood is pumped from the patient's body through an extracorporeal circuit, one component of which is the dialyzer. The dialyzers contain semi-permeable membranes that allow for diffusion and/or ultrafiltration to transport toxins and excess fluid from the blood compartment (fiber lumen) to the dialysate compartment. Dialyzers utilize a counter-current flow in which dialysate and blood flow in opposite directions in the dialyzer. The counter-current flow maintains the concentration gradient across the membrane for waste and fluid removal.

1.4.5. Materials of Use

The FX CorAL dialyzers are classified as external communicating devices having direct contact via circulating blood and chronic long-term use exposure (> 30 days, Classification C) 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 FX CorAL dialyzers' components are composed of the following materials:

Component	Material
Housing	Polypropylene
Potting Resin	Polyurethane
Fiber Bundle	Polysulfone-polyvinylpyrrolidone blend, α-tocopherol (vitamin E)
Sealing Ring	Silicone

Component	Material
Flange	Polypropylene
Blood Port Cap(s)	Polypropylene and 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 FX CorAL 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 FX Coral Dialyzers

Trade Name	Flow Rate Conditions (mL/min)			Typical Urea Clearance (mL/min)
	Qb	Qd	Qf	
FX CorAL 60 Dialyzer	300	500	0	270
FX CorAL 80 Dialyzer	300	500	0	277
FX CorAL 100 Dialyzer	300	500	0	282
FX CorAL 120 Dialyzer	300	500	0	285
FX CorAL 600 Dialyzer	300	500	75	285
FX CorAL 800 Dialyzer	300	500	75	288
FX CorAL 1000 Dialyzer	300	500	75	292

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

FX CorAL 60, 80, 100, and 120 Dialyzers:

The FX CorAL hemodialyzers are intended for single use only for extracorporeal blood purification during intermittent renal replacement therapies hemodialysis (HD), hemodiafiltration (HDF) using pre-, post or mixed-dilution modes, and isolated ultrafiltration for patients suffering from renal insufficiency.

FX CorAL 600, 800, and 1000 Dialyzers:

The FX CorAL hemodiafilters are intended for single use only for extracorporeal blood purification during intermittent renal replacement therapies hemodialysis (HD), hemodiafiltration (HDF) using pre-, post or mixed-dilution modes, and isolated ultrafiltration for patients suffering from renal insufficiency.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the proposed FX CorAL dialyzers are equivalent to the predicate FX CorAL dialyzers (K220721):

- Intended Use and Indications for Use
- Principle of Operation
- Design and Configuration
- Technological Characteristics
- Materials
- Performance Requirements

1.8. Performance Data

The proposed FX CorAL dialyzers are identical to the predicate FX CorAL dialyzers with respect to manufacturing, design, sterilization method, and materials. The proposed labeling changes do not impact the performance of the dialyzers. The data provided in K220721 remains applicable for the performance evaluations.

1.8.1. Biocompatibility Testing

The proposed FX CorAL dialyzers are identical to the predicate FX CorAL dialyzers with respect to manufacturing, design, sterilization method, and materials. The proposed labeling changes do not impact the biological safety of the dialyzers. The data provided in K220721 remains applicable for biological, hematological, and chemical evaluations.

1.8.2. Human Factors Validation Testing

The FX CorAL 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 FX CorAL dialyzers are not electrical mechanical devices.

1.8.4. Software Verification and Validation Testing

Not applicable. The FX CorAL 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 device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the FX CorAL dialyzers are safe and effective for their intended use.