



March 21, 2025

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

Re: K242053

Trade/Device Name: FX CorAL 40 (F00009214); FX CorAL 50 (F00009215)
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: July 12, 2024
Received: February 21, 2025

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,

Gema Gonzalez -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
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Office of Product Evaluation and Quality
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Enclosure

Indications for Use

Submission Number (if known)

K242053

Device Name

FX CorAL 40 (F00009214);
FX CorAL 50 (F00009215)

Indications for Use (Describe)

FX CorAL HD dialyzers are intended for hemodialysis (HD), hemodiafiltration (HDF), hemofiltration (HF), and isolated ultrafiltration in patients, including pediatric patients, with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

Consider body and dialyzer surface area, blood flow, body weight and extracorporeal blood volume when selecting dialyzers for use with pediatric patients.

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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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
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Phone: (781) 460-1087
Fax: (781) 699-9635
Contact Person: Timothy Groves, Senior Lead
Preparation Date: 15 July 2024

1.2. Device Name

Trade Name: FX CorAL 40 (F00009214), FX CorAL 50 (F00009215)
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 secondary predicate devices are the HemoFlow F3 and F4 Dialyzers (K190459). These predicates have not been subject to design-related recalls.

The Gambro Polyflux 6H Dialyzer (K051520) is used as a reference device to support the expanded Indications for Use statement.

1.4. Device Description

1.4.1. Device Identification

The FX CorAL 40 and 50 dialyzers are the subject of this 510(k) and are available in two (2) configurations as shown in Table 1.

Table 1: FX CorAL Dialyzers

Trade Name	Product Number	Surface Area (m²)
FX CorAL 40	F00009214	0.6

Table 1: FX CorAL Dialyzers

Trade Name	Product Number	Surface Area (m ²)
FX CorAL 50	F00009215	1.0

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
Flange	Polypropylene
Blood Port Cap(s)	Polypropylene, Silicone

Component	Material
Dialysate Port Cap(s)	Styrene-Ethylene-Butylene-Styrene, 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 Q_b = blood flow rate, Q_d = dialysate flow rate, and Q_f = filtration flow rate. The Q_f is equal to the ultrafiltration rate (Q_{uf}) plus the substitution flow rate (Q_s), where $Q_s = 0$ 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)
	Q_b	Q_d	Q_f	
FX CorAL 40 Dialyzer	200	500	0	178
FX CorAL 50 Dialyzer	200	500	0	192

1.5. Intended Use

The FX CorAL dialyzers are designed for single use hemodialysis and hemo(dia)filtration for the treatment of acute kidney injury or chronic kidney disease.

1.6. Indications for Use

FX CorAL HD dialyzers are intended for hemodialysis (HD), hemodiafiltration (HDF), hemofiltration (HF), and isolated ultrafiltration in patients, including pediatric patients, with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

Consider body and dialyzer surface area, blood flow, body weight and extracorporeal blood volume when selecting dialyzers for use with pediatric patients.

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), secondary predicate Hemoflow F3 and F4 dialyzers (K190459), and reference Gambro 6H Polflux dialyzer (K051520):

- Intended Use
- Principle of operation
- Design characteristics
- Sterilization method
- 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. Due to design similarities, structural integrity and shipping and distribution testing submitted in K220721 is being leveraged to support the proposed FX CorAL 40 and 50 dialyzers.

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	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 15 min. Samples were taken again after another 15 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.
Blood Compartment Integrity	Evaluate the integrity of the blood compartment

All testing met predetermined acceptance criteria and demonstrated that, like the predicate devices, the FX CorAL dialyzers are safe and effective for their intended use.

1.8.1. Biocompatibility Testing

The materials of the proposed FX CorAL 40 and 50 dialyzers are identical to the predicate FX CorAL dialyzers (K220721). Therefore, a subset of biocompatibility testing was performed to evaluate the smaller surface areas of the proposed dialyzers.

The toxicological risk assessment from the predicate FX CorAL dialyzers was updated to evaluate the biological safety in pediatric patients.

Testing performed to support the biological safety of the FX CorAL 40 and 50 dialyzers:

- Chemical Analysis – Extractables (update to existing documentation)
- Chemical Analysis - Leachables
- ISO Subchronic Toxicity, Short-Term (14-Day) Repeated Exposure
- Genotoxicity, ISO Bacterial Reverse Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Hemocompatibility, Mechanical Hemolysis

1.8.2. Human Factors Validation Testing

A Human Factors assessment was conducted for the FX CorAL dialyzers to demonstrate their 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

A retrospective clinical data analysis performed on the FX CorAL 40 and 50 dialyzers included fourteen (14) pediatric ESRD patients on HD treated for at least 12 consecutive weeks. FX CorAL 40 and 50 dialyzers provided adequate clearance with a mean spKt/V of 2.42 and 2.08 respectively, and all were tolerated.

1.9. Conclusion

The intended use, principle of operation, design characteristics, sterilization method, materials, and performance requirements are substantially equivalent to those of the predicate, secondary predicate, and/or reference devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the FX CorAL 40 and 50 dialyzers are safe and effective for their intended use.