May 11, 2023

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, Massachusetts 02451

Re: K220721
Trade/Device Name: FX CorAL 60, FX CorAL 80, FX CorAL 100, FX CorAL 120, FX CorAL 600, FX CorAL 800, FX CorAL 1000
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 11, 2023
Received: April 11, 2023

Dear Denise Oppermann:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Gema Gonzalez, MS
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220721

Device Name
FX CorAL 60, FX CorAL 80, FX CorAL 100, FX CorAL 120, FX CorAL 600, FX CorAL 800, FX CorAL 1000

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

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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5. 510(K) SUMMARY (K220721)

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.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director
Preparation Date:	11 March 2022

5.2. 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

5.3. Legally Marketed Predicate Device

The legally marketed predicate devices are the F160NR, F180NR, F200NR, and F250NR Optiflux Dialyzers cleared under K162488. These predicates have not been subject to a design-related recall.

The Gambro Polyflux 140H, 170H, and 210H Capillary Dialyzers (K043342) are used as secondary predicate devices to support the expanded Indications for Use statement. The Asahi ViE-U Dialyzer (K162248) is used as a reference device to support the presence of vitamin E.

5.4. Device Description

5.4.1. 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	F00009216	1.4
FX CorAL 80	F00009217	1.8
FX CorAL 100	F00009218	2.2
FX CorAL 120	F00009219	2.5
FX CorAL 600	F00009220	1.6
FX CorAL 800	F00009221	2.0
FX CorAL 1000	F00009222	2.3

5.4.2. 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.

5.4.3. Environment of Use

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

5.4.4. 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.

5.4.5. Materials of Use

The FX CorAL dialyzers are classified as externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, 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* (16 June 2016).

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
Dialysate Port Cap(s)	Styrol-Ethylen-Butylen-Styrol, Polypropylene

5.4.6. 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

5.5. 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.

5.6. Indications for Use

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

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the proposed FX CorAL dialyzers are equivalent to the predicate Optiflux dialyzers (K162488) and the secondary Gambro Polyflux dialyzers (K043342):

- Intended Use
- Design and configuration
- Technological characteristics
- Materials
- Performance requirements

5.8. 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}, β2-Microglobulin	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.

Table 3: Performance Testing Summary

Test Conducted	Test Method Description
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 D4169-16. 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 FX CorAL dialyzers are safe and effective for their intended use.

5.8.1. Biocompatibility Testing

Testing was performed to support the biological safety of the FX CorAL 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.

5.8.2. 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).

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

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

5.8.4. Software Verification and Validation Testing

Not applicable. The FX CorAL dialyzers do not contain software.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

Three (3) outside the U.S. (OUS) clinical trials evaluated safety and performance of the proposed FX CorAL 600 dialyzer. The trials, as well as post-market surveillance, found a comparable safety to the reference dialyzers without new safety signals. The incidence of hypersensitivity and hypersensitivity-like reactions was well below the predefined threshold in each trial and in post-market surveillance.

5.9. Conclusion

The intended use, 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 FX CorAL dialyzers are safe and effective for their intended use.