May 31, 2024

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

Re: K240394
Trade/Device Name: multiFlux 1000 (F00012408)
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: February 8, 2024
Received: May 2, 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.

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)*
K240394

Device Name
multiFlux 1000 (F00012408)

Indications for Use *(Describe)*
The multiFlux 1000 dialyzers are intended for hemodialysis (HD), hemodiafiltration (HDF), hemofiltration (HF), and isolated ultrafiltration in patients with acute kidney injury 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.

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:	08 February 2024

1.2. Device Name

Trade Name:	multiFlux
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 predicate device for the proposed multiFlux 1000 dialyzers is the FX CorAL dialyzers (K220721). This device is not currently subject to a design-related recall.

The Fresenius Optiflux dialyzer (K203062) is being used as a reference device to support the dialysate flange port length of the proposed multiFlux 1000 dialyzers. The NxStage Cartridge Express (K232803) is being used as a reference device to support the reduced blood and dialysate flow rates of the proposed multiFlux 1000 dialyzer.

1.4. Device Description

1.4.1. Device Identification

The multiFlux 1000 dialyzers are the subject of this 510(k) and are available in one (1) configuration as shown in Table 1.

Table 1: multiFlux 1000 Dialyzer

Part Number	Description
F00012408	multiFlux 1000

1.4.2. Device Characteristics

The multiFlux 1000 dialyzers are high-flux, single-use, steam-sterilized hemodialyzers. The dialyzer is 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 multiFlux 1000 dialyzers are used in environments where acute hemodialysis is performed.

1.4.4. Brief Written Description of the Device

The multiFlux 1000 dialyzers are high-flux, sterile devices designed for single-use acute 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 a semi-permeable membrane that allows for diffusion and/or ultrafiltration to transport toxins and excess fluid from the blood compartment (fiber lumen) to the dialysate compartment. The 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 multiFlux 1000 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 multiFlux 1000 dialyzers' components and materials are listed in Table 2.

Table 2: multiFlux 1000 Dialyzer Compents and 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

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 multiFlux 1000 dialyzers. FMCRTG uses sodium clearance as a marker for urea clearance because sodium and urea exhibit similar movement across the membrane. An example of urea clearance data from the Instructions for Use (IFU) is provided in Table 3, 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 3: *in vitro* Urea Clearance for the multiFlux 1000 Dialyzer

Trade Name	Flow Rate Conditions (mL/min)			Typical Urea Clearance (mL/min)
	Qb	Qd	Qf	
multiFlux 1000 dialyzer	200	67	0	67

1.5. Intended Use

The multiFlux 1000 dialyzers are designed for single use hemodialysis and hemo(dia)filtration for the treatment of acute kidney injury.

1.6. Indications for Use

The multiFlux 1000 dialyzers are intended for hemodialysis (HD), hemodiafiltration (HDF), hemofiltration (HF), and isolated ultrafiltration in patients with acute kidney injury when conservative therapy is judged to be inadequate.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the multiFlux 1000 dialyzers are substantially equivalent to those of the predicate FX CorAL dialyzers (K220721):

- Intended Use
- Design
- Principle of Operation
- Materials
- Performance Specifications

1.8. Performance Data

The design of the predicate FX CorAL 600 dialyzer is used as a baseline for the development of the proposed multiFlux 1000 dialyzers. The following changes were made to the predicate device to develop the proposed device:

- Removal of blue colorant from flange component
- Extension of dialysate flange port (for thread interfacing)

These changes will allow users to distinguish between the FX CorAL 600 and multiFlux 1000 dialyzer models. The proposed multiFlux 1000 dialyzer labels will also contain information only pertinent to the acute use environment (i.e., all chronic use environment information will be removed).

All other physical attributes of the multiFlux 1000 dialyzers are identical to the cleared FX CorAL 600 dialyzer. The differences between the predicate and proposed devices do not impact any performance attributes. Therefore, all performance testing from the predicate device 510(k) (K220721) is being leveraged to support the proposed multiFlux 1000 dialyzers.

1.8.1. Biocompatibility Testing

The multiFlux 1000 dialyzers are chemically equivalent to the predicate FX CorAL dialyzers per ANSI/AAMI/ISO 10993-18:2020, Annex C.4.d. The removal of the blue colorant from the flange component does not require additional biocompatibility testing.

1.8.2. Human Factors Validation Testing

The multiFlux 1000 dialyzers were found to be safe and effective for their intended users, uses, and use environments.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The multiFlux 1000 dialyzers are not electrical mechanical devices.

1.8.4. Software Verification and Validation Testing

Not applicable. The multiFlux 1000 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, design, materials, principle of operation, and performance specifications of the multiFlux 1000 dialyzers are substantially equivalent to those of the predicate device. Differences between the multiFlux 1000 dialyzers and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, multiFlux 1000 dialyzers are safe and effective for their intended use.