DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 29, 2015

Fresenius Medical Care North America
Denise Oppermann
Senior Director Regulatory Affairs, Devices
920 Winter Street
Waltham, MA 02451-1457

Re: K152367
Trade/Device Name: Optiflux Dialyzers F160NR, F180NR, F200NR and F250NR
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 20, 2015
Received: August 21, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152367

Device Name
Optiflux Dialyzers F160NR, F180NR, F200NR, and F250NR

Indications for Use *(Describe)*
Optiflux Dialyzers are intended for patients with acute or chronic renal failure 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 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.

5.1. Submitter's Information

Name: Fresenius Medical Care Renal Therapies Group, LLC
Address: 920 Winter Street
Waltham, MA
02451-1457
Phone: (781) 699-4479
Fax: (781) 699-9635
Contact Person: Denise Oppermann, Senior Director
Regulatory Affairs – Devices
Preparation Date: 20 August 2015

5.2. Device Name

Trade Name:	Optiflux® Series of Dialyzers F160NR, F180NR, F200NR, F250NR
Common Name:	Dialyzer, High Permeability with or without Sealed Dialysate System
Classification Name :	High permeability hemodialysis system
Regulatory Class:	Class II per 21 CFR §876.5860
Product Code/ Classification Panel:	KDI Gastroenterology / Urology

5.3. Legally Marketed Predicate Device

The predicate devices are the FMCRTG, LLC Optiflux Ultra dialyzers, model numbers F160, F180, F190, F210 and F230. The Optiflux Ultra dialyzers were cleared in K123262 (06 January 2014). The Optiflux Ultra dialyzers have not been the subject of a design-related recall.

5.4. Device Description

The Optiflux dialyzers are part of the FMCRTG family of single use dialyzers, which allow for the transfer of water and solutes between blood and the dialysate through a semi-

permeable membrane. They Optiflux dialyzers are available in four (4) sizes. The sizes are differentiated by membrane surface area.

5.4.1. Device Identification

The proposed Optiflux series of dialyzers includes the following size dialyzers:

Optiflux® F160NR Dialyzer
Optiflux® F180NR Dialyzer
Optiflux® F200NR Dialyzer
Optiflux® F250NR Dialyzer

5.4.2. Device Characteristics

The proposed Optiflux dialyzers are single use dialyzers manufactured from Advanced Fresenius Polysulfone, polycarbonate, silicone and Polyurethane. The dialyzers are provided with the blood pathway sterile and sterilized using e-beam sterilization.

5.4.3. Environment of Use

The Optiflux dialyzers are used in environments where acute and chronic hemodialysis is performed.

5.4.4. Brief Written Description of the Devices

The principle of hemodialysis involves the diffusion of solutes across a semi-permeable membrane. Dialyzers use a counter-current flow, where the dialysate is flowing in the opposite direction to blood flow in the extracorporeal circuit. Counter-current flow maintains the concentration gradient across the membrane for waste removal (diffusion) and fluid removal (ultrafiltration).

5.4.5. Materials of Use

The Optiflux dialyzers are manufactured from Advanced Fresenius Polysulfone, polycarbonate, polyurethane and silicone. The Optiflux dialyzer are classified as an external communicating device with prolonged exposure (>24 hrs to ≤30 days) to circulating blood.

5.4.6. Key Performance Specifications/Characteristics

Urea clearance is a key performance specification of the Optiflux dialyzers. FMCRTG uses sodium clearance as a marker for urea clearance as they exhibit similar movement across a membrane. Table 1 provides typical sodium clearance data for the Optiflux series of dialyzers.

Table 1: In vitro Urea Clearance Typical for the Optiflux Dialyzer Models (Qb= 300mL/min, Qd= 500mL/min, UFR=0mL/min)

Trade Name	Typical Urea Clearance (Sodium Used as Marker)
Optiflux F160NR Dialyzer	271
Optiflux F180NR Dialyzer	277
Optiflux F200NR Dialyzer	280
Optiflux F250NR Dialyzer	287

5.5. Intended Use

Optiflux dialyzers are designed for single use acute and chronic hemodialysis.

5.6. Indications for Use

Optiflux dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

5.7. Comparison of Technological Characteristics with the Predicate Device

The proposed Optiflux dialyzers and the predicate Optiflux Ultra dialyzers (K123262) have the following equivalent technological characteristics:

- The same intended use including the same indications
- Similar design and configuration
- Same basic scientific technology and principles of operation
- Same sterilization method, packaging and sterility label claims
- Same materials – Advanced Fresenius Polysulfone (PS), polycarbonate (PC), polyurethane (PU) and silicone (SI).

5.8. Performance Data

Performance testing was conducted in accordance with ISO 8637:2010. Results of the testing listed below support the determination of substantial equivalence.

- Performance testing – clearance testing, sieving coefficient, ultrafiltration performance and membrane performance
- Structural integrity testing – positive and negative pressure decay testing and blood compartment integrity
- Biological safety testing (biocompatibility)
- Sterility and pyrogenicity testing.

5.8.1. Biocompatibility Testing

The following testing was performed to support the biocompatibility of the dialyzers:

- Chemical analysis – extractables and leachables
- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Chronic Toxicity
- Genotoxicity
- Hemocompatibility
- Risk assessment of potential toxicity

5.8.2. Animal Studies

No animal studies were performed in support of the Optiflux dialyzers.

5.8.3. Clinical Studies

No clinical studies were performed in support of the Optiflux dialyzers.

5.9. Conclusions

Based on the information and data provided in this Traditional 510(k), the Optiflux dialyzers are substantially equivalent in intended use, indications for use, design, principle of operation, technology, materials and performance to the predicate Optiflux Ultra dialyzers (K123262) and are safe and effective for their intended use.