



Food and Drug Administration  
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Silver Spring, MD 20993-0002

April 6, 2017

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

Re: K162488  
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: March 3, 2017  
Received: March 6, 2017

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,

  
**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

## Indications for Use

510(k) Number (if known)

K162488

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.

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## 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.

### 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:** August 30 2016

### 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/** KDI  
**Classification Panel:** Gastroenterology / Urology

### Legally Marketed Predicate Device

The predicate devices are the FMCRTG, LLC Optiflux dialyzers, model numbers F160NR, F180NR, F200NR and F250NR. The Optiflux dialyzers were cleared under K152367 (29 October 2015). The Optiflux dialyzers have not been the subject of a design-related recall.

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

### **Device Identification**

The proposed Optiflux series of dialyzers includes the following sizes/models

- 0500316E - Optiflux<sup>®</sup> F160NR Dialyzer
- 0500318E - Optiflux<sup>®</sup> F180NR Dialyzer
- 0500320E - Optiflux<sup>®</sup> F200NR Dialyzer
- 0500325E - Optiflux<sup>®</sup> F250NR Dialyzer

### **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 non-pyrogenic. The dialyzers are sterilized using e-beam radiation.

### **Environment of Use**

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

### **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 the blood flow in the extracorporeal circuit. Counter-current flow maintains the concentration gradient across the membrane for waste removal (diffusion) and fluid removal (ultrafiltration).

### **Materials of Use**

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

### **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 sodium and urea exhibit similar movement across a membrane. [Table 1](#) provides sodium clearance data from the instructions for use (IFU) for the Optiflux series of dialyzers.

**Table 1: In vitro Urea Clearance from the Optiflux Dialyzer**  
**Instructions for Use ( $Q_b = 300\text{mL/min}$ ,  $Q_d = 500\text{mL/min}$ ,  $UFR = 0\text{mL/min}$ )**

| Trade Name               | Urea Clearance<br>(Sodium Used as Marker) |
|--------------------------|-------------------------------------------|
| Optiflux F160NR Dialyzer | 271                                       |
| Optiflux F180NR Dialyzer | 277                                       |
| Optiflux F200NR Dialyzer | 280                                       |
| Optiflux F250NR Dialyzer | 287                                       |

### Intended Use

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

### Indications for Use

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

### Comparison of Technological Characteristics with the Predicate Device

The proposed Optiflux dialyzers and the predicate Optiflux dialyzers (K152367) have the following equivalent technological characteristics:

- Intended use including the same indications for use
- Design and configuration
- Basic scientific technology and principles of operation
- Sterilization method, packaging and sterility label claims
- Same materials – Advanced Fresenius Polysulfone (PSF), polycarbonate (PC), polyurethane (PU) and silicone (SI). This submission adds an additional supplier of polysulfone raw material for manufacture of the dialyzer fibers.

### Performance Data

Performance testing was conducted in accordance with ISO 8637:2010. Results of 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 (membrane integrity)

- Biological safety testing (biocompatibility)
- Sterility and pyrogenicity testing

### **Biocompatibility Testing**

The following testing was performed to support the biological safety of the polysulfone supplier change:

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

### **Animal Studies**

No animal studies were performed in support of the supplier change.

### **Clinical Studies**

No clinical studies were performed in support of the supplier change.

### **Conclusions**

Based on the information and data provided in this Traditional 510(k), the proposed Optiflux dialyzers are substantially equivalent in intended use, indications for use, design, principle of operation, technology, materials and performance to the predicate Optiflux dialyzers (K152367). The dialyzers remain safe and effective for their intended use.