Section 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 in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92. A copy of this summary is also provided in Appendix 2.

5.1 Submitter's Information

Name:	Fresenius Medical Care North America
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 Renal Therapies
Date of Preparation:	03 June 2013

5.2 Device Name

Trade Name:	**Optiflux® Ultra F160, F180, F190, F210, F230**
Common Name:	Dialyzer, High Permeability with or without Sealed Dialysate System
Product Code/Classification Panel:	KDI Gastroenterology-Urology
Classification Name:	21 CFR§876.5860 High Permeability Hemodialysis System

5.3 Legally Marketed Predicate Devices (unmodified devices)

Fresenius Optiflux® F250NR, K082414 (10-28-2008)
Baxter Xenium XPH dialyzers, K083778 (02-20-2009)

5.4 Device Description

The Optiflux Ultra dialyzers are the next generation of the Fresenius Optiflux family of single use dialyzers, which allow for the transfer of water and solutes between the blood and the dialysate through a semipermeable membrane. Available in five sizes, the dialyzers are differentiated by membrane surface area.

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5.5 Indications for Use

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

5.6 Technological Characteristics

The Optiflux Ultra dialyzers and Fresenius Optiflux F250NR dialyzer (K082414) have equivalent technological characteristics:

- Design/Configuration
- Basic Scientific Technology – membrane of microcrimped, hollow fiber, Advanced Fresenius Polysulfone®
- Sterility – E-Beam, single use, non- pyrogenic
- Materials – polyurethane (PU), polysulfone (PS), polycarbonate (PC), and silicone (SI)

The Optiflux Ultra dialyzers, Fresenius Optiflux F250NR dialyzer (K082414), and Baxter Xenium XPH dialyzers (K083778), have equivalent technological characteristics:

- Intended Use
- Design Characteristics – effective surface area, priming volume

5.7 Performance Data

Testing was selected through the application of a risk management process, appropriate guidance documents and relevant standards. Results of validation and verification testing support the determination of substantial equivalence:

- Sterility and non-pyrogenicity testing
- Structural integrity – filter assembly positive and negative pressure testing and blood compartment integrity (transmembrane pressure testing)
- Performance – clearance testing, ultrafiltration performance testing, membrane performance
- Biological Safety – Biocompatibility testing

5.8 Conclusion

Based on the information and data provided in this Traditional 510(k), the Optiflux Ultra dialyzers are substantially equivalent in design, principle of operation, technology, materials to the predicate Fresenius Optiflux F250NR dialyzer (K082414). The Optiflux Ultra dialyzers are substantially equivalent in intended use, indications for use, and performance to the predicate devices, Fresenius Optiflux F250NR dialyzer (K082414) and Baxter Xenium dialyzers (K083778), and are safe and effective for their intended use.

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

January 6, 2014

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

Re: K123262
Trade/Device Name: Fresenius Optiflux® Ultra F160, F180, F190, F210, F230 dialyzers
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: December 18, 2013
Received: December 20, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -S

for

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

Section 4 Indications for Use Statement

510(k) Number: K123262

Device Name:

Fresenius Optiflux® Ultra F160, F180, F190, F210, F230 dialyzers

Indications for Use: Optiflux Ultra F160, F180, F190, F210, F230 dialyzers

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

☒ Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

☐ Over-the-Counter Use
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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