FRESENIUS MEDICAL CARE

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 Part 807.92.

Submitter's Information

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Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs - Devices Renal Therapies Group
Date of Preparation:	July 1, 2014

Device/Trade Name:	Wand Assembly
Common Name:	Connector Cap
Classification Name:	High permeability hemodialysis system ;
Classification Number:	Class II per 21 CFR § 876.5860
Product Code/Classification Panel:	KDI; Gastroenterology/Urology Panel

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Legally Marketed Predicate Device (unmodified device)
2008 series Hemodialysis Machines: 2008T Hemodialysis Machine (K121341), 2008K@home Hemodialysis Machine with bibag (K124035), and 2008K Hemodialysis Machine (K994267).

Device Description
The Acid Concentrate, Bicarbonate Concentrate and Acetic Acid wands are sub-assemblies intended to be used with the concentrate and acetic acid canisters as accessories to the 2008 Series Hemodialysis Machines.

The wands allow the 2008 Series Hemodialysis Machines to attach to the canisters and supply bicarbonate (blue wand), acid concentrate (red wand), and acetic acid (white wand).

During a dialysis treatment, the blue and red Canister-Wand Assemblies provide connectivity to supply the 2008 Series Hemodialysis Machines with Acid Concentrate and Bicarbonate Concentrate solutions. The Hemodialysis Machine will dilute these solutions with Reverse Osmosis (RO) water to produce the final dialysate solution.

The white acetic acid Wand Assembly is used to supply Acetic Acid to the 2008 Series Hemodialysis Machines while running an Acid Cleaning Program as part of regular maintenance procedures. The Acid Clean Program flushes the machine with white distilled vinegar, 5% acetic or 5% citric acid for 10-60 minutes to prevent build of bicarbonate in the hydraulic system after treatment. During the cleaning program, the patient is not connected to the hemodialysis machine.

The device description information included in this submission conforms to the applicable requirements of 21 CFR Section 876.5860, declared guidance and standards.

Indications for Use
The Wand Assemblies are intended to be used with the 2008 Series Hemodialysis Machines to provide a fluid pathway for the concentrates and acetic acid from the canisters to the acid and bicarbonate lines of the 2008 Series Hemodialysis Machines. The Wand Assemblies are designed to be used as an accessory to the 2008 Series Hemodialysis Machines for the patients receiving dialysis therapy for acute and chronic renal failure.

Intended Use
The intended use of the Wand Assemblies is described in this submission the same as the intended use of the Wand Assemblies on the predicate devices. Both devices are intended to

be used with the 2008 Series Hemodialysis Machines as accessories to provide a fluid pathway between the concentrate and acetic acid canisters and the 2008 Series Hemodialysis Machine.

Technological Characteristics

The subject Wand Assemblies and the predicate assemblies have similar technological characteristics:

- Intended Use – As an accessory to provide a concentrate fluid pathway between the concentrate and acetic acid canisters and the 2008 series Hemodialysis Machine.
- Design/Configuration – Patient Fluid contacting and non-patient contacting components designed and sub-assembled to provide an interface for connection between concentrate and acetic acid canisters and the 2008 Series Hemodialysis Machines concentrate lines.
- Fundamental Scientific Technology/Operating Principle: The Acid Concentrate, Bicarbonate and Acetic Acid wands are sub-assemblies intended to be used with canisters as accessories of the 2008 Series Hemodialysis Machines. The Canister-Wand Assemblies allow the 2008 Series Hemodialysis Machines to attach to the canisters and supply the machine with bicarbonate (blue wand), acid concentrate (red wand), and acetic acid (white wand).
- Materials – Fluid-Contacting: Polypropylene, Silicone, PVDF, Non-Fluid Contacting: HDPE, Stainless Steel.

The differences between the subject Wand Assemblies and Predicate Wand Assemblies are as follows:

- Design/Configuration - The proposed wand assemblies are comprised of similar component types as the predicates. The jug adapter portions of the proposed wand assemblies have different mold geometry.
- Materials – The proposed wand assemblies utilize different colorants and a different polypropylene resin. All material types remain the same as the predicate.

Performance Data

Testing was selected through the application of a risk management process, applicable guidance documents and relevant standards. The following tests were conducted to support the determination of substantial equivalence:

- Performance – Functional Verification
- Biological Safety (per ISO 10993 and G95-1) – Biocompatibility (GLP) and Chemical Evaluations

Conclusion

Results from the functional testing and biocompatibility testing demonstrate that the differences between the proposed and the predicate device do not raise any new concerns with regard to safety or effectiveness.

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FMC-RTG concludes that, within the meaning of the Medical Device Amendments Act of 1976, the Wand Assemblies are substantially equivalent to the assemblies cleared for use as accessories of the 2008 Series Hemodialysis Machine.

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

July 7, 2014

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

Re: K133299
Trade/Device Name: Wand Assembly
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: June 2, 2014
Received: June 3, 2014

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

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)*
K133299

Device Name
Wand Assembly

Indications for Use *(Describe)*
The Wand Assemblies are intended to be used with the 2008 Series Hemodialysis Machines to provide a fluid pathway for the concentrates and acetic acid from the canisters to the acid and bicarbonate lines of the 2008 Series Hemodialysis Machines. The Wand Assemblies are designed to be used as an accessory to the 2008 Series Hemodialysis Machines for the patients receiving dialysis therapy for acute and chronic renal failure.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.07.07 07:37:56 -04'00'

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