K131050

DEC 27 2013

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. **Date** April 12, 2013

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843 United States
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Nnamdi Nwachukwu Regulatory Affairs Engineer
Phone:	(978) 332-8477
Fax:	(978) 687-4750
Manufacturer:	NxStage GmbH & Co. KG Anna-Vandenhoeck-Ring 24 37081 Goettingen Bundesrepublik Deutschland
FDA Establishment Registration Number:	An application for an establishment registration number will be submitted prior to commercialization.
Sterilization Site:	Steris Isomedix 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage® 1.6m^2 Dialyzer
Common/Usual Name:	Dialyzer, High Permeability
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Product Code :	78 KDI – Dialyzer, High Permeability with or Without

	Sealed Dialysis System
Submission Type:	510(k)
Device Class:	II
Device Panel:	Gastroenterology-Urology (GU)/ Gastro-Renal (GRDB)

D. Predicate Devices:

K061837 NxStage Cartridge Express
K113023 NxStage Streamline Airless System Set w/ Pre-Attached Dialyzer
K062079 Baxter Xenium Dialyzer

E. Substantial Equivalence:

The proposed NxStage® 1.6m^2 Dialyzer is substantially equivalent in design, function and operation to the identified predicates.

F. Device Description/Indications for Use:

The proposed device is a single use high flux (permeability) hollow-fiber dialyzer.

Indications for use: The dialyzer is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. There are no known contraindications.

G. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as the predicate devices.

Device Comparison Table				
Parameter	**NxStage 1.6m² Dialyzer Subject of this 510(k)**	**Predicate Device NxStage Cartridge Express K061837**	**Predicate Device Streamline Airless System Set with Pre-attached dialyzer K113023**	**Predicate Device Baxter Xenium Dialyzer 150 K062079**
Indications for Use	The dialyzer is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. There are no known contraindications.	The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The System is also indicated for hemodialysis with or without ultrafiltration in the home.	The single use blood tubing set with pre-attached dialyzer is indicated for use with the B. Braun Dialog Series hemodialysis systems for the treatment of acute and chronic renal failure. There are no known contraindications.	Hemodialysis with Xenium dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.
Principle of Operation	Removal of solutes via diffusion or convection	Removal of solutes via diffusion or convection	Removal of solutes via diffusion or convection	Removal of solutes via diffusion or convection
Product Configuration	Single use disposable dialyzer with standard dialysis connectors that are connected to blood tubing sets prior to use.	Single use disposable consisting of a pre-attached dialyzer and tubing set for use on the NxStage System One.	Single use disposable consisting of a pre-attached dialyzer and tubing set for use on the B. Braun Dialog Series hemodialysis systems.	Single use disposable dialyzer with standard dialysis connectors that are connected to blood tubing sets prior to use.
How Supplied	Individually packaged dialyzer.	Dialyzer pre-connected to disposable NxStage Cartridge tubing set.	Dialyzer pre-connected to disposable B. Braun tubing set.	Individually packaged dialyzer.

Device Comparison Table				
Parameter	**NxStage 1.6m^2 Dialyzer**	**Predicate Device NxStage Cartridge Express (K061837)**	**Predicate Device Streamline Airless System Set with Pre-attached dialyzer (K113023)**	**Predicate Device Baxter Xenium Dialyzer 150 (K062079)**
Connectors	Standard ISO8637 DIN Blood and Dialysate Hansen Connectors	Blood and dialysate lines pre-bonded	Blood lines pre-bonded, Standard ISO8637 Dialysate Hansen Connector	Standard ISO8637 DIN Blood and Dialysate Hansen Connector
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Fibers	Polyethersulfone Membrana Purema H	Polyethersulfone Membrana Purema H	Polyethersulfone Membrana Purema H	Polyethersulfone Membrana Purema H
Fiber ID	200 µm	200 µm	200 µm	200 µm
Fiber Wall Thickness	30 µm	30 µm	30 µm	30 µm
Effective Surface Area	1.6 m^2	1.6 m^2	1.6 m^2	1.5 m^2
Priming Volume	91 ml	91 ml	91 ml	91 ml
Max. TMP	500 mmHg	500 mmHg	500 mmHg	500 mmHg

H. Summary of Non-Clinical Test/Performance Testing - Bench

The information and data provided in this submission clearly describe the proposed device and demonstrate that the device is adequately designed for the labeled indications for use and is substantially equivalent to the predicate devices. Performance, verification and validation testing was conducted to characterize performance of the proposed device, consistent with FDA's *Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers,* dated August 7, 1998, and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate devices and is suitable for the labeled indication for 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

December 27, 2013

NxStage Medical, Inc.
Laura F. Plath
Regulatory Affairs Manager
350 Merrimack Street
Lawrence, MA 01843

Re: K131050
Trade/Device Name: NxStage® 1.6m^2 Dialyzer
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: December 6, 2013
Received: December 9, 2013

Dear Laura F. Plath,

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 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. 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 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,

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): K131050

Device Name: NxStage® 1.6m^2 Dialyzer

Indications for Use: The dialyzer is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. There are no known contraindications.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Benjamin R. Fisher -S
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