510k Summary

K123395

NxStage Medical, Inc.
NxStage System One Low Volume Cartridge Express
510(k) Premarket Notification

MAR 0 7 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:	March 4, 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:	Mary Lou Stroumbos Regulatory Affairs Manager
Phone: **Fax:**	(978) 687-4872 (978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843 United States
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One Low Volume Cartridge Express
Common/Usual Name:	Dialyzer with High Permeability Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Product Code:	78 KDI – Dialyzer, High Permeability with our without Sealed Dialysate System
Device Classification:	Class II
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

D. Predicate Devices:

NxStage Cartridge Express	K061387
Gambro Cartridge Blood Set Low Weight - Low Volume Set	K100364
Gambro Prisma M60 Set	K032431
Minntech HF Junior Hemofilter	K071298
Minntech High Permeability Dialyzer	K923312

E. Substantial Equivalence:

The NxStage System One Low Volume Cartridge Express device is substantially equivalent in design, function and operation to the identified predicates.

F. Device Description/Indications for Use:

The NxStage System One Low Volume Cartridge Express is a single-use extracorporeal blood circuit and fluid management device with a pre-attached high flux (permeability) hollow-fiber filter that mounts integrally within the NxStage Cycler.

Indications for use:

The NxStage System One Low Volume Cartridge Express is indicated for use only with the NxStage System One, in a chronic care dialysis facility or acute care unit. It is indicated for use in adult patients for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration.

All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

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 System One Low Volume Cartridge Express**	**Predicate Device NxStage Cartridge Express K061837**	**Predicate Device *Gambro Cartridge Blood Set Low Weight Low Volume K100364**	**Predicate Device Gambro Prisma M60 Disposable Set K032431**
PRODUCT	Disposable extracorporeal circuit for use with the NxStage System One. Consists of dialyzer and disposable NxStage Cartridge.	Disposable extracorporeal circuit for use with the NxStage System One. Consists of dialyzer and disposable NxStage Cartridge.	Disposable, extracorporeal circuit for use with the Phoenix Dialysis Delivery System	Disposable, extracorporeal circuit for use with the Prismaflex system. Consists of AN69 hollow fiber hemofilter dialyzer and tubing lines.

Device Comparison Table				
Parameter	**NxStage System One Low Volume Cartridge Express**	**Predicate Device NxStage Cartridge Express K061837**	**Predicate Device *Gambro Cartridge Blood Set Low Weight Low Volume K100364**	**Predicate Device Gambro Prisma M60 Disposable Set K032431**
INDICATIONS FOR USE	The NxStage System One Low Volume Cartridge Express is indicated for use only with the NxStage System One in a chronic care dialysis facility or acute care unit. It is indicated for use in adult patients for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.	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 our without ultrafiltration in the home. All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.	The Gambro Cartridge Blood Set Low Weight-Low Volume is intended for single use in a hemodialysis treatment using the Phoenix Dialysis Delivery System. The Low-Weight Low Volume model is used when a low extra-corporeal blood volume is recommended. The Low Weight-Low Volume model with a priming volume of 40 ml is indicated for patients with a body weight greater than 15 kg and lower or equal to 20 kg.	Indicated for use with the Prisma control unit in providing continuous fluid management and renal replacement therapies for patients who have acute renal failure, fluid overload, or both.

Device Comparison Table				
Parameter	**NxStage System One Low Volume Cartridge Express**	**Predicate Device NxStage Cartridge Express K061837**	**Predicate Device *Gambro Cartridge Blood Set Low Weight Low Volume K100364**	**Predicate Device Gambro Prisma M60 Disposable Set K032431**
THERAPIES INDICATED	Continuous/ intermittent hemofiltration and/or ultrafiltration. Continuous/ intermittent hemodialysis and/or ultrafiltration and slow continuous ultrafiltration	Continuous/ intermittent hemofiltration and/or ultrafiltration. Continuous/ intermittent hemodialysis and/or ultrafiltration and slow continuous ultrafiltration	Hemodialysis	SCUF-slow continuous ultrafiltration CVVH-continuous venovenous hemofiltration CVVHD-continuous hemodialysis CVVHDF-continuous venovenous hemodiafiltration
PRINCIPLE OF OPERATION	Removal of solutes via diffusion or convection	Removal of solutes via diffusion or convection	Removal of solutes via diffusion	Removal of solutes via diffusion and/or convection
HOW SUPPLIED	Dialyzer pre-connected to disposable NxStage Cartridge	Dialyzer pre-connected to disposable NxStage Cartridge	Sterile non pyrogenic blood pathway is supplied sealed in plastic package	The Prismaflex M60 set consists of an AN69 hollow fiber hemofilter dialyzer and tubing lines
PRIMING VOLUME	15 mL (filter) 70 mL (cartridge set total)	91 mL (filter) 175 – 200 mL (cartridge set total)	40 mL (blood tubing set)	42mL ± 10% (filter) 93 mL (Set total)

***Note:** K100364 does not feature a pre-attached dialyzer.

Device Comparison Table					
Parameter	**NxStage System One Low Volume Cartridge Express**	**Predicate Device NxStage Cartridge Express K061837**	**Predicate Device Gambro Prisma M60 Disposable Set K032431**	**Predicate Device Minntech HF Junior Hemofilter K071298**	**Predicate Device Minntech High Permeability Dialyzer K923312**
FIBERS	Polyethersulfone	Polyethersulfone	Acrylonitrile and sodium methallyl sulfonate copolymer	Polysulfone	Polysulfone
FIBER INTERNAL DIAMETER	200 µm	200 µm	240 µm	200 µm	200 µm
FIBER WALL THIICKNESS	30 µm	30 µm	50 µm	Not available	Not available
FIBER LENGTH	10 cm	23 cm	27 cm overall dimension	15 cm overall dimension	9.42 cm
EFFECTIVE SURFACE AREA	0.21 m^2	1.6 m^2	0.60 m^2	0.09 m^2	0.30 m^2
PRIMING VOLUME	15 ml (filter) 70 ml (cartridge)	91 ml (filter) 175 – 200 ml (cartridge)	42 ml ± 10% (blood priming volume in filter) (93 ml blood volume in set)	8 ml (filter)	28 ml (filter)
MAX. TMP	500 mmHg	500 mmHg	450 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 substantially equivalent to predicate devices. Performance, verification and validation testing was conducted to characterize performance of the proposed device. This included testing for the integrity of the strength between connections (pressure leak testing); priming volume assessment; tensile testing of joints and materials of tubing segments; tubing clamps testing; kink resistance testing; hemocompatibility

testing; pressure drop, ultrafiltration rates, clearance determination, and sieving coefficients testing, as well as simulated use testing. All predetermined acceptance criteria were met. Results of this testing also document that the proposed NxStage System One Low Volume Cartridge Express device is substantially equivalent to the predicate devices and is suitable for the labeled indications 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

March 7, 2013

NxStage Medical, Inc.
% Ms. Mary Lou Stroumbos
Regulatory Affairs Manager
350 Merrimack Street
LAWRENCE MA 01843

Re: K123395
Trade/Device Name: NxStage System One Low Volume Cartridge Express
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: January 31, 2013
Received: February 5, 2013

Dear Ms. Stroumbos:

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,

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): K123395

Device Name: NxStage System One Low Volume Cartridge Express

Indications for Use: The NxStage System One Low Volume Cartridge Express is indicated for use only with the NxStage System One in a chronic care dialysis facility or acute care unit. It is indicated for use in adult patients for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration.

All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

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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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123395