NxStage® Medical, Inc.
NxStage PureFlow™ SL
510(k) Summary

SEP 19 2011

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.

Date of Summary: August 26, 2011

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, 5th Floor Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Sr. Regulatory Affairs Associate
Phone: **Fax:**	(978) 687-4872 (978) 687-4750
Manufacturer:	Entrada Group/NxStage Carretera Fresnillo A Plateros, KM2 Fresnillo, Zacatecas 99059 Mexico
FDA Establishment Registration Number:	3006546166
Sterilization Site:	Steris Isomedix, Inc. 1000 S. Sarah Place Ontario, CA 91761

B. Subject Device Name:

Trade/Proprietary Name:	NxStage PureFlow SL
Common/Usual Name:	Subsystem, proportioning
Classification Name:	Hemodialysis systems and accessories
Regulation Number:	21 CFR 876.5820
Product Code:	78 FKR
Device Classification:	Class II
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

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C. Substantial Equivalence:

This submission is a Special 510(k) Device Modification as described in the FDA's Guidance document entitled, "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this Special 510(k), NxStage has provided certification of compliance to 21 CFR §820.30 Design Control Requirements. Design validation testing was performed to ensure that the NxStage PureFlow SL (PFSL) module with modification to increase the mix to use (MTU) time of the prepared dialysate from 72-hours to 96-hours meets design specifications. The NxStage PFSL module with modifications has been compared to the legally marketed PFSL predicate device as cleared through K080919 (October 15, 2008) and was found to be substantially equivalent.

D. Device Description/Indications for Use:

The NxStage PFSL module is an optional accessory to the NxStage System One that is used to treat water for hemodialysis per ANSI/AAMI/ISO 13959:2009 and ANSI/AAMI/ISO 26722:2009 and proportion it with dialysate concentrate to produce dialysate per ANSI/AAMI/ISO 11663:2009. The PFSL module consists of the Control Unit (CU), the water Pre-Treatment Unit, the optional OPTA Kit, the Purification Pack (PAK), and the Dialysate Sack (SAK) with Dialysate Concentrate.

Indications for use:

The NxStage PureFlow SL module is an optional accessory to the NxStage System One that prepares dialysate for use during hemodialysis, as prescribed by the physician.

E. Technological Characteristics:

The indications for use of the proposed device and of the predicate device are identical. There is no change to the indications for use or intended use of the PureFlow SL module, and the modification has no affect on the fundamental scientific technology of the device. The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device.

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

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance and verification and validation testing was conducted to characterize performance of the proposed device. This included stability, bioburden and endotoxin testing on validation batches of dialysate to support the extension of the MTU duration to 96-hours. All predetermined acceptance criteria were met. The NxStage PureFlow SL meets the ANSI/AAMI/ISO 11663:2009 requirements of < 100 CFU/ml bioburden and < 0.5 EU/ml endotoxin (LAL). Results of this testing have documented that the proposed NxStage PureFlow SL with 96-hour MTU time is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Mary Lou Stroumbos
Sr. Regulatory Affairs Associate
NxStage Medical, Inc.
439 South Union Street, 5th Floor
LAWRENCE MA 01843

SEP 19 2011

Re: K111174
Trade/Device Name: NxStage® PureFlow™ SL
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FKR
Dated: August 26, 2011
Received: August 29, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
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): K111174

Device Name: NxStage® PureFlow™ SL

Indications for Use: The NxStage PureFlow SL module is an optional accessory to the NxStage System One™ that prepares dialysate for use during hemodialysis, as prescribed by the physician.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111174