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K080919
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NxStage Medical, Inc.
NxStage PureFlow SL (PFSL)
510(k) Device Modification

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. 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:	Michael Doyle Manager, Regulatory Affairs
Phone: Fax:	(978) 687-4746 (978) 687-4750
Manufacturing Site:	Entrada Group/NxStage Carretera Fresnillo A Plateros, KM2 Fresnillo, Zacatecas 99059 Mexico
FDA Establishment Registration Number:	3006546166
Manufacturing/Sterilization Site:	Steris Isomedix, Inc. 1000 S. Sarah Place Ontario, CA 91761

B. Device Name:

Trade/Proprietary Name:	NxStage PureFlow SL
Common/Usual Name:	Subsystem, proportioning
Classification Name:	Hemodialysis Systems & Accessories
Regulation Number:	876.5820
Product Code:	78 FKR
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

C. Substantial Equivalence/Predicate Devices:

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 modifications meets design specifications. The NxStage PFSL module with modifications has been compared to the legally marketed predicated device as cleared through K060296 (March 31, 2006) 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 and proportion it with dialysate concentrate to produce dialysate per ANSI/AAMI RD52:2004 and ANSI/AAMI RD62: 2006. The PFSL module consists of the Control Unit (CU), the water Pre-Treatment Unit, the Purification Pack (PAK), and the Dialysate Sack (SAK) with Dialysate Concentrate.

Indications for use:

The NxStage PFSL 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 proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar components and features also used in the predicate device.

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

NxStage Medical, Inc. 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, verification and validation testing was conducted to characterize performance of the proposed PFSL to provide a basis of comparison to the predicate device as all features are not identical. Results of this testing have documented that the proposed PFSL module is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Mr. Michael J. Doyle
Manager, Regulatory Affairs
NxStage Medical, Inc.
439 South Union Street, 5th Floor
LAWRENCE MA 01843

Re: K080919
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 12, 2008
Received: August 13, 2008

Dear Mr. Doyle:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080919

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___ (Part 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080919