510(k) Summary

K122051
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NxStage Medical, Inc.
NxStage System One
Special 510(k) Device Modification

APR 2 3 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. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Regulatory Affairs Manager
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

NxStage Medical, Inc.
NxStage System One
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B. Device Name:

Trade/Proprietary Name:	NxStage® System One™
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	78 KDI
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

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 System One with modification to increase the therapy fluid pump rate from 200 ml/min (12 L/hr) to 300 ml/min (18 L/hr) meets design specifications. The NxStage System One has been compared to the legally marketed predicate device as cleared through K093069 (October 23, 2010) and was found to be substantially equivalent.

D. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit and the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility and is also indicated for hemodialysis with or without ultrafiltration in the home. The NxStage System One is also indicated for Therapeutic Plasma Exchange in a clinical environment.

Indications for use:

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 NxStage System One is also indicated for Therapeutic Plasma Exchange in a clinical environment.

All treatments must be administered under physician's prescription, and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing 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 features a therapy fluid pump rate of 300 ml/min (18 L/hr) and is designed with similar software, components and features also used in 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, verification and validation testing was conducted to characterize performance of the proposed device. This included verification, safety, performance, and software testing. All predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage System One with a therapy fluid pump rate of 300 ml/min (18 L/hr) 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2013

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

Re: K122051
Trade/Device Name: NxStage System One
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: March 22, 2013
Received: March 25, 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,

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

INDICATIONS FOR USE

510(k) Number (if known): K122051

Device Name: NxStage System One

Indications for Use:

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 NxStage System One is also indicated for Therapeutic Plasma Exchange in a clinical environment.

All treatments must be administered under physician's prescription, and must be observed 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 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122051