NxStage Medical, Inc.
NxStage System One with TPE Cartridge
510(k) Premarket Notification Submission

October 15, 2010

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 United States
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	MaryLou Stroumbos Regulatory Affairs Associate
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 439 South Union St. 5th Floor Lawrence, MA 01843 United States
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix 1000 S. Sarah Place Ontario, CA 91761

OCT 2 3 2010

B. Device Name:

Trade/Proprietary Name:	NxStage System One with Therapeutic Plasma Exchange Cartridge
Device:	Dialyzer with High Permeability Hemodialysis System
Regulation Description:	High Permeability Hemodialysis System
Regulation Medical Specialty:	Gastroenterology/Urology Devices
Review Panel:	Gastroenterology/Urology
Product Code:	KDI LKN
Submission Type:	510(k)
Regulation Number:	864.5860
Device Class:	2

C. Substantial Equivalence:

The proposed NxStage System One with Therapeutic Plasma Exchange Cartridge is substantially equivalent to the identified predicates indicated for therapeutic plasma exchange.

D. Device Description/Indications for Use:

The NxStage System One with Therapeutic Plasma Exchange Cartridge provides therapeutic plasma exchange therapy when used with a commercially available TPE filter. The machine that controls the therapy is called the Cycler. The blood tubing set is the NxStage TPE Cartridge. The TPE Cartridge is a single use extracorporeal blood circuit and fluid management device available without a pre-attached filter. Therapeutic plasma exchange requires the use of a commercially available therapeutic plasma exchange filter such as the Asahi Plasmaflo.

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 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 a 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 devices.

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 and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed NxStage System One with TPE Cartridge 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

AUG 10 2012

Re: K093069
Trade/Device Name: NxStage System One with Cartridge
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: October 15, 2010
Received: October 18, 2010

Dear Ms. Stroumbos:

This letter corrects our substantially equivalent letter of October 23, 2010.

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 (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 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,

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): K093069

Device Name: NxStage System One with Cartridge

Indications for Use:

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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, Gastro-Renal, and Urological Devices
510(k) Number K093069