Section VII: 510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, Suite 501 Lawrence, MA 01843
Phone:	(978) 687-4700
Fax:	(978) 687-4800
Contact Person:	Norma LeMay Manager, Regulatory Affairs
Date of Preparation:	July 13, 2004

B. Device Name:

Trade Name:	NxStage Water Purification System
Common/Usual Name:	Water Purification System
Classification Name:	Water Purification System for Hemodialysis (Class II medical device under 21 CFR 875.5665, (Product Code 78 FIP)

C. Substantial Equivalence/Predicate Devices:

The proposed NxStage Water Purification System is substantially equivalent to the following legally marketed predicate devices previously cleared by FDA:

- AmeriWater Portable RO+ Model MROS09, (K030059, cleared 04/07/03)
- HydroPure Deionization Systems, (K022747, cleared 02/11/03)
- Water & Power Technologies of Texas, Inc. (K994292, cleared 01/02/01)
- Total Water Treatment System, (K002045, cleared 02/16/01)

NxStage Medical, Inc.
Water Purification System
510(k) Premarket Notification

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D. Device Description/Indications for Use:

The NxStage Water Purification System is a stand-alone water System designed to pre-treat and purify water for use with hemodialysis applications. The purified water can be used in preparation of dialysate, equipment rinsing and disinfection, and dialyzer reprocessing. The System is intended to be used in a variety of environments, including an acute or chronic care facility or the home. There are no known contraindications with the use of the NxStage Water Purification System.

The System is single patient use and is comprised of three major components: 1) a pretreatment system which consists of a check valve, sediment filter and air vent to remove trapped air, sediment, and any impurities, 2) a Pump Controller unit which contains the control and safety software that controls the flow rate, monitors pressure, water quality and system operation and 3) a replaceable resin system that removes organic and inorganic chemical contaminants as well as microbiological contaminants such as bacteria and endotoxins. The System flow rate is specified by the end user.

With proper use, the System will produce water that meets or exceeds the requirements of the standard issued by the American National Standard Institute and the Association for the Advancement of Medical Instrumentation: ANSI/AAMI RD62:2001, Water Treatment Equipment for Hemodialysis Applications.

Indications for use:

The NxStage Water Purification System is a stand-alone water treatment system designed to pretreat and purify water for use in hemodialysis applications. The purified water can be used in preparation of dialysate, equipment rinsing and disinfection, and dialyzer reprocessing. It is intended to be used in a variety of environments, including acute or chronic care facility or home.

E. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate devices. The proposed device is designed and assembled with components commonly found in the predicate devices.

F. Summary of Non-Clinical Test/Performance Testing

NxStage Medical 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 testing was conducted to characterize performance of the proposed NxStage Water Purification System to provide a basis of comparison to the predicate devices. Results of the

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performance testing have demonstrated that the NxStage Water Purification System 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
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2004

NxStage Medical, Inc.
c/o Mr. Casey Conry
Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K042089
Trade/Device Name: NxStage Water Purification System
Regulation Number: 21 CFR §876.5665
Regulation Name: Water Purification System for Dialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: November 1, 2004
Received: November 2, 2004

Dear Mr. Conry:

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 (Premarket Approval), 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): K042089

Device Name: NxStage Water Purification System

Indications for Use:

The NxStage Water Purification System is a stand-alone water treatment system designed to pretreat and purify water for use in hemodialysis applications. The purified water can be used in preparation of dialysate, equipment rinsing and disinfection, and dialyzer reprocessing. It is intended to be used in a variety of environments, including acute or chronic care facility or home.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042089