MAR 17 2005

NxStage Medical, Inc.
NxStage Dialysate Prep Module
510(k) Premarket Notification

Section VIII: 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:	December 10, 2004

B. Device Name:

Trade Name:	NxStage Dialysate Preparation Module
Common/Usual Name:	Subsystem, proportioning
Classification Name:	Hemodialysis System & Accessories (Class II medical device under 21 CFR 875.5820, (Product Code 78 FKR)

C. Substantial Equivalence/Predicate Devices:

The NxStage Dialysate Prep Module is substantially equivalent to the following legally marketed predicate devices previously cleared by FDA:

- Aksys PHD System, K010131 (cleared on 03/26/02)
- Fresenius 2008K Hemodialysis System, K994267 (cleared on 03/16/00)
- Gambro Bicarbonate Module BCM-10, K810127 (cleared on 02/25/81)

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D. Device Description/Indications for Use:

The NxStage Dialysate Prep Module is an optional accessory to the NxStage System One that pre-treats and purifies water that mixes with concentrate to produce dialysate meeting the requirements of the ANSI/AAMI Standards, RD52:2004 and RD62:2001. The dialysate is to be used with the NxStage System One during hemodialysis therapies.

Indications for use:

The NxStage Dialysate Preparation Module is an optional accessory to the NxStage System One that prepares dialysate for use during hemodialysis, as prescribed by the physician.

There are no known contraindications with the use of the NxStage Dialysate Preparation Module.

E. Technological Characteristics:

The proposed Prep Module has the same technological characteristics and is similar in design and configuration as compared to the predicate devices. It uses purified AAMI water that mixes with AAMI concentrate to produce AAMI dialysate. The proposed device is designed and assembled with components commonly found in the predicate devices. Importantly, the NxStage Prep Module incorporates the proper safety features, such as conductivity measurement, automatic safety clamp, mix to use timer, and ultrafilters and I.V. sterilization filters to insure dialysate purity.

F. Summary of Non-Clinical Test/Performance Testing

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 indication for use.

As there is no technological differences as compared to the predicate devices, performance testing was deemed appropriate and was conducted to characterize the performance of the proposed Prep Module to provide a basis of comparison to the predicate devices. The Prep Module utilizes FDA cleared devices with minor modifications, and additional components which are simple to operate using the provided device labeling. Verification and Validation testing, which includes simulated use testing, sufficiently demonstrates that the Prep Module can be used safely as intended. All testing performed is summarized in Section V of this 510(k) submission. Results of the testing presented in this 510(k) have demonstrated that the NxStage Prep Module is substantially equivalent to the predicate devices and is suitable for the labeled indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Ms. Norma LeMay
Manager, Regulatory Affairs
NxStage® Medical, Inc.
439 South Union Street, 5th Floor
LAWRENCE MA 01843

Re: K043436
Trade/Device Name: NxStage® Dialysate Preparation Module
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO and FKR
Dated: March 3, 2005
Received: March 4, 2005

Dear Ms. LeMay:

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.

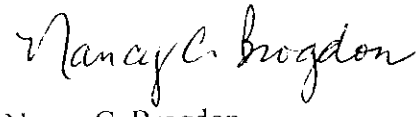
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

Sincerely yours,



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): K043436

Device Name: NxStage Dialysate Preparation Module

Indications for Use:

The NxStage Dialysate Preparation 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043436