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

Section IX: 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.

JUN 2 4 2005

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:	May 26, 2005

B. Device Name:

Trade Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System 21 CFR 875.5860, (Product Code 78 KDI)

C. Substantial Equivalence/Predicate Devices:

The NxStage System One is substantially equivalent to the following legally marketed predicate device previously cleared by FDA:

- NxStage System One, K041424 (cleared on 07/02/04)

D. Device Description/Indications for Use:

The NxStage System One consists of the NxStage Cycler and the NxStage Cartridge Extracorporeal Blood and Fluid Circuit with or without a pre-attached high permeability filter. The NxStage Cycler is an electro-mechanical device that

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interfaces with the NxStage Cartridge. The NxStage Cartridge is a single-use extracorporeal blood circuit and fluid management device that mounts integrally within the NxStage Cycler. The System is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility and is also indicated for hemodialysis and/or ultrafiltration in the home.

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.

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:

There are no changes in the technological characteristics of the NxStage System One as a result of this 510(k) submission. This submission is to expand the indication for use to include hemodialysis in the home.

F. Summary of Clinical Data obtained:

The clinical study consisted of thirty two subjects (ITT population) at six investigational sites. Parameters used to establish the substantial equivalence of the NxStage System One in a home environment were the ability to deliver the clinically prescribed amount of therapy and the incidence of adverse events. The same treatment regimen performed in an in-center environment served as a basis for comparison, with each patient serving as his or her own control.

NxStage believes that the information and clinical data provided in this 510(k) submission demonstrates that the device is adequately designed for the expansion in the indication for use to include hemodialysis in the home, and is substantially equivalent to the predicate device in terms of efficacy, accuracy, and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2005

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

Re: K050525
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: May 26, 2005
Received: May 27, 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

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): K050525

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.

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)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050525