OCT 2 8 2003

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

K032356

Section VIII: 510(k) Summary

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 Sr. Regulatory Specialist
Date of Preparation:	July 29, 2003

B. Device Name:

Trade Name:	NxStage System One with Cartridge Express
Common/Usual Name:	Dialyzer with High Permeability Hemodialysis System
Classification Name:	Dialyzer, High Permeability with or without Sealed Dialysate System (21 CFR 875.5860, Product Code 78 KDI)

C. Substantial Equivalence/Predicate Devices:

The NxStage Cartridge Express is substantially equivalent to the following legally marketed predicate devices previously cleared by FDA:

- NxStage Cartridge Express (K014152, cleared 12/10/02)
- Gambro Prisma CFM System Disposable Tubing Set (K946279, cleared 02/10/97)

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D. Device Description/Intended Use:

The NxStage System One consists of the NxStage Cycler and the NxStage Cartridge Extracorporeal Blood and Fluid Circuit.

The NxStage Cycler is an electro-mechanical device that 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 NxStage Cartridge Express is a single-use extracorporeal blood circuit and fluid management device with a pre-attached high flux (permeability) hollow-fiber filter.

The System (and all components) is intended for treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration in both acute and chronic environments, as prescribed by the treating physician.

Indications for use:

The NxStage System One is indicated for treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. All treatments must be administered by a health care provider, under physician's prescription.

E. Technological Characteristics:

The NxStage Cartridge Express has the same technological characteristics and is similar in design and configuration as compared to the predicate devices. There are no material changes to the NxStage Cartridge Express as described and cleared through K014152, as a result of this 510(k) submission. The only difference between the proposed Cartridge Express as compared to the predicate (K014152) is the expansion in intended use to include hemodialysis.

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. Performance testing was conducted to characterize the performance of the NxStage Cartridge Express during hemodialysis to provide a basis of comparison to the predicate devices. Results of the performance testing have documented that the NxStage Cartridge Express 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

OCT 2 8 2003

Ms. Norma LeMay
Senior Regulatory Specialist
NxStage Medical, Inc.
439 South Union Street
5th Floor
LAWRENCE MA 01843

Re: K032356
Trade/Device Name: NxStage System One With Cartridge Express
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: July 29, 2003
Received: July 30, 2003

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K032356

Device Name: NxStage System One with Cartridge Express

Indication for Use: *The NxStage System One is indicated for treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. All treatments must be administered by a health care provider, under physician's prescription.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032356