K030470
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NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Section VIII: Summary of Safety and Effectiveness

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

A. Submitter's Information:

JUL 0 7 2003

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:	January 30, 2003

B. Device Name:

Trade Name:	NxStage System One
Common/Usual Name:	High Permeability Hemodialysis System
Classification Name:	System, Dialysate Delivery, Sealed (21 CFR 875.5860, Product Code FII)

C. Substantial Equivalence/Predicate Devices:

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

- NxStage Therapy System (K020858, cleared 04/17/02)
- B. Braun Diapact CRRT (K973322, cleared 11/10/98)
- Baxter (SPS), Model 550 (K872364, cleared 10/13/87)

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D. Device Description/Indications for 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 system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration.

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 prescription.

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 System One to provide a basis of comparison to the predicate devices. Results of the performance testing have documented that the proposed NxStage System One 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

JUL - 7 2003

NxStage Medical, Inc.
c/o Intertek Testing Services
Donald James Sherratt
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K030470
Trade/Device Name: NxStage® System One
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Product Code: 78 FII
Dated: July 3, 2003
Received: July 7, 2003

Dear Mr. Sherratt:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030470

Device Name: NxStage System One

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 prescription.*

(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 K030470

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