

JUL - 2 2004

SECTION 7  
510(K) SUMMARY

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The contents of this 510(k) summary have been provided in conformance with 21 CFR §807.92.

**Date:** May 27, 2004

**Common/Usual Name:** Hemodialysis System

**Trade/Proprietary Name:** NxStage System One

**Classification Name & Device Classification:** Dialyzer, High Permeability with or without Dialysate System; Class II

**Product Code:** KDI

**21 CFR Ref.:** 876.5860

**Device Panel:** Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

**510(k) Sponsor & Owner/Operator:** NxStage Medical, Inc  
439 South Union St, Suite 501  
South Lawrence, MA 01843  
Owner/Operator No. 9045797

**Contact Person:** Norma LeMay  
Manager, Regulatory Affairs

**Device Description:**

The NxStage System One, consisting of hardware, software and a sterile disposable cartridge, is indicated for the 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.

**Substantial Equivalence:**

This submission is a Special 510(k) Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Pre-Market Notifications." In support of this 510(k), NxStage has provided certification of compliance to 21 CFR 820.30 Design Control requirements. The NxStage System One, with one modified warning, has been compared to the Fresenius 2008K and the baseline NxStage System One (K030470) and found to be substantially equivalent.

**Conclusion:**

Based on the device's indication for use, a comparison of descriptive and technological characteristics to the baseline and Fresenius 2008K, and design control certification, the modified NxStage System One device labeling has been shown to meet the minimum requirements that are considered acceptable for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 2 2004

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

Re: K041424

Trade/Device Name: NxStage System One  
Regulation Number: 21 CFR §876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: 78 KDI  
Dated: May 27, 2004  
Received: May 28, 2004

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.

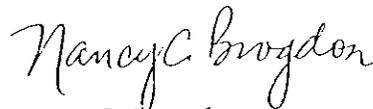
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
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): K041424

Device Name: NxStage System One

Indications for Use:

*The NxStage System One is indicated for the 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.*

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041424