K012510
p.1/2

OCT 1 9 2001

SECTION 11

510(K) SUMMARY

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, NxStage, Inc. is required to submit with this Pre-Market Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." NxStage chooses to submit a summary of information respecting safety and effectiveness.

Date:	August 3, 2001
Common/Usual Name:	Hemofiltration system
Trade/Proprietary Name:	LifeMate™ Hemofiltration System
Classification Name & Device Classification:	Dialyzer, High Permeabilty 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 S. Lawrence, MA 01843 Owner/Operator No. Not yet assigned
Contact Person:	Karen St.Onge (Contact Person) Director of Quality Assurance

Device Description:
The LifeMate™ Hemofiltration System, consisting of hardware, software and a sterile disposable cartridge, is indicated for treatment of renal failure or fluid

overload using hemofiltration 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 Medical has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Design Verification testing has been performed to ensure that the modified device meets design specifications. The modified LifeMate™ System has been compared to the LifeMate™ System as cleared in K001283.

Conclusion:
Based on the device indications for use, comparison of descriptive and technological characteristics, and design control certification, the modified LifeMate™ Hemofiltration System has been shown to meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Ms. Karen St.Onge
Director, Quality Assurance/
Regulatory Affairs
NxSTAGE Medical, Inc.
439 South Union Street, Suite 501
Lawrence, Massachusetts 01843

Re: K012510
Trade/Device Name: LifeMate™ Hemofiltration System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: September 18, 2001
Received: September 19, 2001

Dear Ms. St.Onge:

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 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:

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" (21 CFR Part 807.97). 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

Page 1 of 1

510(k) Number (if known): K012510

Device Name: LifeMate Hemofiltration System

Indications for Use:

The LifeMate™ Hemofiltration System is indicated for treatment of renal failure or fluid overload using hemofiltration 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 K012510

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)