NxStage Medical, Inc.
Premixed Dialysate
510(k) Premarket Notification

OCT 21 2002

Section VI: 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:

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 Senior Regulatory Affairs Specialist
Date of Preparation:	August 23, 2002

B. Device Name:

Trade Name:	NxStage Premixed Dialysate
Common/Usual Name:	Premixed Dialysate
Classification Name:	Hemodialysis system and accessories (21CFR 876.5820)
Product Code:	78 KP0 - Dialysate Concentrate for Hemodialysis (Liquid or Powder)

C. Predicate Device Name:

The predicate devices for the NxStage Premixed Dialysate are:

- NxStage Dialysate Concentrate (K013655, 02/04/02)
- Baxter Premixed Dialysate for Hemodiafiltration (K910270, 4/18/1991)
- PrismaSate Dialysis Solutions (K013448, 01/15/02)

D. Device Description/Indications for Use:

The NxStage Premixed Dialysate Solutions are a family of premixed dialysate solutions which are sterile, non-pyrogenic solutions to be provided in single use flexible PVC bags varying in sizes from 1000 to 5000ml. The premixed dialysate solutions are intended for use with renal replacement therapy systems that utilize sterile premixed dialysate. A family of dialysate solutions will allow the physician to prescribe different electrolyte compositions that meet the specific needs of individual patients.

The NxStage Premixed Dialysate Solutions are manufactured by B. Braun Schiwa located in Glandorf, Germany.

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Indications for Use
NxStage Premixed Dialysate is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Does the new device have the same Indication Statement?

YES – The indication for use for the NxStage Premixed Dialysate Solutions is equivalent to that of the predicate devices.

Proposed NxStage Premixed Dialysate
NxStage Premixed Dialysate is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

NxStage Dialysate Concentrate (K013655)
NxStage Dialysate Concentrate, after dilution, is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

Baxter Premixed Dialysate for Hemodiafiltration (K910270)
Baxter Premixed Dialysate is indicated for acute dialysis modalities such as continuous arteriovenous hemodiafiltration (CAVHD), and continuous venous-venous hemodiafiltration (CVVHD), when treating acute renal failure patients with hypervolemia and uremia that requires high solute clearance.

PrismaSate Dialysis Solution (K013448)
Gambro PrismaSate Solutions are indicated for use as a dialysate in continuous renal replacement therapy.

2. Does the new device have the same technological characteristics (e.g., design, materials, etc.)

Yes – The chemical composition ranges, for the common constituents, of the NxStage Premixed Dialysate are identical to that of the PrismaSate Dialysis Solutions, K013448 and therefore raise no new types of safety or effectiveness issues. As described in this submission, there are no major differences in the technology characteristics as compared to the predicate devices.

3. Are the descriptive characteristics precise enough to ensure equivalence?

No – The chemical composition ranges, for the common constituents, of the NxStage Premixed Dialysate are identical to that of the PrismaSate Dialysis Solutions, K013448 and similar to the Baxter Premixed Dialysate, K910270 and the NxStage Concentrate, K013655. However, variations in product formulations and sterilization methods may impact final characteristics of the product.

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4. Are performance data available to assess equivalence?

YES – NxStage Medical, Inc. has provided data for a validation batch of the NxStage Premixed Dialysate Solutions produced under controlled manufacturing conditions representative of those to be used to produce the dialysate for commercial distribution. Results of the batch validation assays have demonstrated that the dialysate manufacturer is capable of producing a solution meeting all end-product specifications.

5. Does performance data demonstrate equivalence?

YES – NxStage Medical, Inc. believes that the information and data provided in this submission clearly describes the NxStage Premixed Dialysate Solutions and demonstrates that the solutions are substantially equivalent to the predicate devices.

F. Safety Summary

Both the bag label and Instructions for Use include indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the NxStage Premixed Dialysate Solutions. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2002

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

Re: K022913
Trade/Device Name: NxStage Premixed Dialysate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: October 4, 2002
Received: October 7, 2002

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 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 STATEMENT

510(k) Number (if known): K022913

Device Name: NxStage Premixed Dialysate

Indications for Use: NxStage Premixed Dialysate is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

(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 C. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022913