**NxStage Medical, Inc.**
**NxStage Travel Warmer**
**510(k) Premarket Notification**

AUG 2 4 2007

## Section 5 - 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<br>Lawrence, MA 01843 |
| Phone: | (978) 687-4700 |
| Fax: | (978) 687-4800 |
| Contact Person: | Norma LeMay<br>Manager, Regulatory Affairs |
| Date of Preparation: | May 4, 2007 |

### B. Device Name:

| | |
|---|---|
| Trade Name: | NxStage Travel Warmer |
| Common/Usual Name: | Monitor, Temperature, Dialysis |
| Classification Name: | Hemodialysis System and Accessories (876.5820)<br>Product Code: 78 FLA |

### C. Substantial Equivalence/Predicate Devices:

The proposed NxStage Travel Warmer is substantially equivalent to the NxStage Warmer cleared through K012832 on 10/24/2001 and K020858 on 4/17/2002.

### D. Device Description/Indications for Use:

The NxStage Travel Warmer and Travel Warmer Disposable Set are accessories to the NxStage System One used to warm dialysate. The Travel Warmer is for use with the NxStage System One only and is not used to warm blood or blood products. The Travel Warmer consists of an electro-mechanical warming unit and a

## Section 5 - 510(k) Summary

single-use disposable.

***Indications for use:***

*The NxStage Travel Warmer and Travel Warmer Disposable Set are accessories to the NxStage System One used to warm dialysate prior to administration.*

E. Technological Characteristics:

**The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.**

F. Summary of Non-Clinical Test/Performance Testing - Bench

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 indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed NxStage Travel Warmer to provide a basis of comparison to the predicate device as all features are not identical. Results of the all testing have documented that the proposed NxStage Travel Warmer is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 24 2007

Mr. Paul Clark
Director of Clinical and Regulatory Affairs
NxStage Medical, Inc.
439 South Union Street, 5th Floor
LAWRENCE MA 01843-2800

Re: K071263
Trade/Device Name: NxStage Travel Warmer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Dated: August 6, 2007
Received: August 8, 2007

Dear Mr. Clark:

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 (Premarket Approval), it may be subject to such 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 this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K071263

Device Name: NxStage Travel Warmer

Indications for Use: The NxStage Travel Warmer and Travel Warmer Disposable Set are accessories to the NxStage System One used to warm dialysate prior to administration.

**Prescription Use** ___X___ **AND/OR** **Over-The-Counter Use**_____
**(Part 21 CFR 801 Subpart D)** **(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)**

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071263