K090255
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NxStage Medical, Inc.
Blood Tubing Sets
510(k) Device Modification

FEB 10 2009

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, 5th Floor Lawrence, MA 01843 United States
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Michael Doyle Manager, Regulatory Affairs
Phone: Fax:	(978) 687-4746 (978) 687-4750
Manufacturing Site:	MEDIMEXICO, S. DE R.L. DE C.V. Av. Valle imperial No. 10523 Parque industrial Valle Sur Tijuana, B.C., Mexico 22180
FDA Establishment Registration Number:	9616074
Manufacturing/Sterilization Site:	Kawasumi Laboratories Co. Ltd. 55/26-27 m-13 Phaholyothin Rd. Km-46 Klong Nueng, Klong Luang Pratumtanee, Thailand 12120
FDA Establishment Registration Number:	9680437
Manufacturing/Sterilization Site:	Kawasumi Laboratories Co. Ltd. 48 Moo 8 Ratchasima-Chokchai Rd., Tambon Tha-ang, Amphur Chokchai, Nakhorn Rachasima, Thailand 30190
FDA Establishment Registration Number:	9615908
Sterilization Site:	Steris Corporation Isomedix Services, Inc. 1000 S. Sarah Place Ontario, CA 91761

FDA Establishment Registration Number:	Contract sterilizer
Sterilization Site:	STERIS Corporation Isomedix Service, Inc. 7685 St. Andrews Ave. San Diego, CA 92154
FDA Establishment Registration Number:	Contract sterilizer

B. Device Name:

Trade/Proprietary Name:	Blood Tubing Sets
Common/Usual Name:	Tubing sets
Classification Name:	Sets, Tubing, Blood, With and Without Anti-Regurgitation Valve
Regulation Number:	876.5820
Product Code:	FJK
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

C. Substantial Equivalence/Predicate Devices:

The subject blood tubing set is substantially equivalent to the following legally marketed predicate device, previously cleared by the FDA;

- Arterial-Venous Blood Tubing Sets, K080807, July 18, 2008

D. Device Description/Indications for Use:

The blood tubing sets consist of a family of products which are used during extracorporeal procedures to provide a means to connect blood access devices to a hemodialysis or hemofiltration machine and a hemodialyzer or hemofilter. To facilitate a hemodialysis procedure, for example, the arterial and/or venous blood tubing sets may contain features such as air trap chambers, filters, injection sites, pump segments, heparin infusion lines, saline administration lines, pressure pillows, priming sets, and pressure monitoring lines with or without transducer protectors. Numerous product codes are produced to accommodate various manufacturer's dialysis machines, as well as differing clinical preferences and clinical procedures.

Indications for use:

The blood tubing sets are indicated for use with a medically prescribed hemodialyzer. The suitability of a particular configuration is the responsibility of the physician in charge.

E. Technological Characteristics:

The subject device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The subject device is designed with similar components and features that are also used in the predicate device.

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

NxStage Medical, Inc. believes that the information and data provided in this submission clearly describes the subject 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 subject blood tubing set to provide a basis of comparison to the predicate device as all features are not identical. Results of this testing have documented that the subject blood tubing set is substantially equivalent to the predicate device 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

FEB 10 2009

Mr. Michael Doyle
Manager, Regulatory Affairs
NxStage Medical, Inc.
439 South Union Street, 5th Floor
LAWRENCE MA 01843

Re: K090255
Trade/Device Name: Blood Tubing Sets
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK, KOC
Dated: January 30, 2009
Received: February 2, 2009

Dear Mr. Doyle:

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 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting 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): K090255

Device Name: Blood Tubing Sets (Sterile Fluid Path)

Indications for Use:

The blood tubing sets are indicated for use with a medically prescribed hemodialyzer. The suitability of a particular configuration is the responsibility of the physician in charge.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090255