DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 11, 2014

NxStage Medical, Inc.
Laura F. Plath
Regulatory Affairs Manager
350 Merrimack Street
Lawrence, MA 01843

Re: K134019
Trade/Device Name: Dual Lumen needle/Dual Lumen Buttonhole needle
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: July 30, 2014
Received: July 31, 2014

Dear Laura F. Plath,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): not known at the time of submission

Device Name: Medisystems Dual Lumen Needle

Indications for Use: The Medisystems Dual Lumen Needle is indicated for use as a vascular access device for dialysis procedures**.**

Device Name: Medisystems Dual Lumen Buttonhole Needle

Indications for Use: The Medisystems Dual Lumen Buttonhole Needle is indicated for use as a vascular access device for dialysis procedures using a constant-site or “buttonhole” method of needle insertion.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

Date: December 27, 2013

A. Submitter's Information:

Name:	NxStage Medical, Inc.
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FDA Establishment Owner/Operator Number:	9045797
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Manufacturing and Sterilization Site:	Kawasumi Laboratories Co. (Thailand) Ltd. 48 Moo 8 Ratchasima-Chokchai Rd., Tambon Tha-ang, Amphur Chokchai, Nakhorn Rachasima, Thailand
FDA Establishment Registration Number:	9615908

B. Device Name:

Trade/Proprietary Name:	Medisystems onesite Dual Lumen Needle with MasterGuard® Anti-Stick Needle Protector Medisystems onesite Dual Lumen Buttonhole Needle with SteriPick®
Device:	Needle, fistula
Regulation Description:	Blood access device and accessories.
Regulation Medical Specialty:	Gastroenterology/Urology Devices
Review Panel:	Gastroenterology/Urology
Product Code:	FIE
Submission Type:	Traditional 510(k)

Regulation Number:	876.5540
Device Class:	II

C. Substantial Equivalence:

These two proposed devices are substantially equivalent to two predicate devices: Medisystems Buttonhole Needles cleared under K990803 and the Cordis Corp. Bionics Bi-Flo double lumen needle cleared under K801355. The proposed Dual Lumen Needle and Dual Lumen Buttonhole Needle are substantially equivalent to these two cleared predicates.

D. Device Description/Indications for Use:

The proposed devices are to be used as a vascular access device for dialysis procedures using either a standard needle insertion technique (for Dual Lumen Needle) or a constant-site or "buttonhole" method of insertion (for Dual Lumen Buttonhole Needle).

Indications for use:

Dual Lumen Needle:	The Medisystems Dual Lumen Needle is indicated for use as a vascular access device for dialysis procedures.
Dual Lumen Buttonhole Needle:	The Medisystems Dual Lumen Buttonhole Needle is indicated for use as a vascular access device for dialysis procedures using a constant-site or "buttonhole" method of needle insertion.

E. Technological Characteristics:

The proposed devices have the same technological characteristics and are similar in design and configuration as compared to the predicate devices.

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

NxStage believes that the information and data provided in this submission clearly describes the proposed devices and demonstrates that the devices are adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed devices and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed devices are substantially equivalent to the predicate devices and are suitable for the labeled indications for use.