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

May 9, 2017

NxStage Medical, Inc.
Randall Covill
Regulatory Affairs Manager
350 Merrimack Street
Lawrence, MA 01843

Re: K170469
Trade/Device Name: NxStage System One Plus
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: February 17, 2017
Received: February 21, 2017

Dear Randall Covill:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170469

Device Name
NxStage System One Plus

Indications for Use *(Describe)*
The NxStage System One Plus is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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NxStage Medical, Inc.
NxStage System One Plus
Traditional 510(k) Premarket Notification

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 Prepared: February 15, 2017

Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Randall Covill Regulatory Affairs Manager
Phone:	(978) 298-4163
Fax: e-mail:	(978) 687-4750 rcovill@nxstage.com
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

Device Name:

Trade/Proprietary Name:	NxStage System One Plus
Common/Usual Name:	Hemodialysis System
Classification Name: Regulation Number: Product Code: Device Classification: Device Panel:	High Permeability Hemodialysis System 876.5860 78 KDI Class II Gastroenterology/Urology

Comparison to Predicate:
The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K141752 (December 19, 2014) and was found to be substantially equivalent.

Device Description:
The NxStage System One Plus is comprised of the NxStage Cycler, an electromechanical control unit;

NxStage Medical, Inc.
NxStage System One Plus
Traditional 510(k) Premarket Notification

the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One Plus is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One Plus is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The NxStage System One Plus is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

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 components and features also used in the predicate device.

Summary of Non-Clinical Test/Performance Testing – Bench

Non-clinical bench and performance testing included.

- Bench testing
    - Software testing – testing used to characterize software performance
        - Shutdown Alarm Verification
        - Cycler Software Test
        - NSO Plus User Interface Software Verification Test
        - NSO Plus Alarm and Warning Verification Test
        - NSO Plus Data Communication Verification Test
        - UIC Alarm Processor SW Test
        - Cycler 4.12 Software Change Verification Test
        - NSO Plus White Box Test
        - NxStage System One Software White Box Test
    - Electrical standards used – list of electrical standards
        - ANSI / AAMI ES 60601-1: 2005 (R2012)
        - IEC 60601-1:Ed 3.1
        - IEC 60601-1-2:2007
        - IEC 60601-1-6
        - IEC 60601-1-8
        - IEC 60601-1-11:2015
        - IEC 60601-2-16: 2012
        - ISO 11137-1:2006
        - EN ISO 14971:2007
        - IEC 62366:2007, 1st Ed

NxStage Medical, Inc.
NxStage System One Plus
Traditional 510(k) Premarket Notification

The non-invasive blood pressure measuring module meets the following standards:

- IEC 80601-2-30 Ed. 1.0
- IEC 81060-2:2013

o Device performance – list of testing used to characterize device performance

- System Performance Test
- Control Subsystem Test
- Safety Subsystem Test
- Mechanical Fastener Verification
- Pressure Subsystem Test
- Electronics Subsystem Test
- Operating Temperature Test
- Thermal Testing on the Cycler Test
- Flow Chart Test
- Cycler Labeling Test
- NiBP Subsystem Test
- System One Chronic User Guide Warning and Precaution Verification Test
- NSO Plus User Interface Subsystem Test
- NX1000-10 Chronic NxStage System One, Basic Safety & Essential Performance Regulatory Test
- Operating Options Test
- System One NiBP Essential Performance Standards Compliance Test
- Chemical Resistance Test
- Ship Testing

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. Verification and validation was conducted to characterize the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.