August 9, 2019

NxStage Medical, Inc.
Christina Marabella
Associate Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K183158
Trade/Device Name: NxStage Cartridge Express with Speedswap
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: July 11, 2019
Received: July 12, 2019

Dear Christina Marabella:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K183158

Device Name
NxStage Cartridge Express with Speedswap

Indications for Use *(Describe)*

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

The NxStage Cartridge Express with Speedswap is an optional accessory device to be used exclusively with the NxStage System One for facilitating the removal and replacement of a flow-compromised filter during treatment of acute and chronic renal failure or fluid overload. The device would be used when hemofiltration, hemodialysis, and /or ultrafiltration may become disrupted.

All treatments must be administered under a physician's prescription and must be observed 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.
Cartridge Express with Speedswap
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:	August 9, 2019
Submitter's Information	
Name:	NxStage Medical, Inc.
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Manufacturer	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix 1000 S. Sarah Place Ontario, CA 91761 Sterigenics Fort Worth 3125 Wichita Ct. Fort Worth, TX 76140USA Steris 1435 Isomedix Place El Paso, TX 79936

Device Name:

Trade/Proprietary Name:	NxStage Cartridge Express with Speedswap
Common/Usual Name:	Dialyzer with High Permeability Hemodialysis System
Classification Name	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Product Code:	KDI
Device Classification:	Class II
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

Predicate Device:

The predicate device is the currently marketed NxStage System One Cartridge Express, K061837 FDA cleared on July 31, 2006.

Substantial Equivalence:

The NxStage Cartridge Express with Speedswap has the same intended use and utilizes the same fundamental scientific technology as the identified predicate. The proposed cartridge has been compared to the legally marketed predicate cartridge and is substantially equivalent in design, function, and operation to the identified predicate, K061837.

Device Description/Indications for Use:

Device Description:
The NxStage Cartridge Express with Speedswap is a single use extracorporeal blood circuit and fluid management device with a pre-attached detachable high permeability hollow-fiber filter. The proposed feature, "Speedswap" is a feature in the cartridge design that will allow the user to exchange the filter that is becoming clotted or clogged with a new filter that has been manually primed.

A kit will be required to perform the filter exchange. The proposed optional kit will consist of a filter with tubing connections for manual priming along with a waste bag to collect used saline. The nurse has the option of using the proposed cartridge without using the Speedswap feature. The functionality of the proposed cartridge is the same as the predicate Cartridge. Exchanging a used filter is optional and the facility can choose to dispose of the entire cartridge instead of exchanging the Filter.

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

The NxStage Cartridge Express with Speedswap is an optional accessory device to be used exclusively with the NxStage System One for facilitating the removal and replacement of a flow-compromised filter during treatment of acute and chronic renal failure or fluid overload. The device would be used when hemofiltration, hemodialysis, and /or ultrafiltration may become disrupted.

All treatments must be administered under a physician's prescription and must be observed 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 with a minor difference to allow for the used filter to be exchanged. The proposed device is designed with similar components and features also used in the predicate device.

Table 1
Substantial Equivalence Comparison Table

Feature	NxStage Cartridge Express with Speedswap Proposed Device	NxStage Cartridge Express K061837 - Predicate	COMPARISON
Intended Use	For treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration	For treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration	**SAME**
Therapies Indicated	Continuous/intermittent hemofiltration and/or ultrafiltration Continuous/intermittent hemodialysis and/or ultrafiltration and slow continuous ultrafiltration	Continuous/intermittent hemofiltration and/or ultrafiltration Continuous/intermittent hemodialysis and/or ultrafiltration and slow continuous ultrafiltration	**SAME**
Principal of Operation	Removal of solutes via diffusion and/or convection	Removal of solutes via diffusion and/or convection	**SAME**
Filter (Dialyzer)	NxStage® 1.6m^2 Dialyzer	NxStage® 1.6m^2 Dialyzer	**SAME**
Sterilization Method	Gamma; 10^{-6} SAL	Gamma; 10^{-6} SAL	**SAME**
Product Configuration	Disposable extracorporeal circuit with pre-attached detachable filter for use with the NxStage System One. This Cartridge is configured with connections to allow the filter to be exchanged.	Disposable extracorporeal circuit with pre-attached filter for use with the NxStage System One.	**MODIFIED**
Indications for Use	The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute care facility. The NxStage Cartridge Express with Speedswap is an optional accessory device to be used exclusively with the NxStage System One for facilitating the removal and replacement of a flow-compromised filter during treatment of acute and chronic renal failure or fluid overload. The device would be used when hemofiltration, hemodialysis, and /or ultrafiltration may become disrupted. All treatments must be administered under a physician's prescription and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.	The NxStage System One 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 hemodialysis with or without ultrafiltration in the home. All treatments must be administered under a physician's prescription, and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.	**MODIFIED**

Summary of Non-Clinical Test / Performance Testing - Bench

Performance Testing

Performance testing was conducted in accordance with ISO 8638:2010.

The following tests were performed to support performance

- Cartridge integrity tests:
  - Cartridge Pressure Leak Test
  - Solvent bond tensile tests
- Simulated use test
- Kink Resistance Test
- Ship Testing
- Blood Line Priming Volume Assessment
- Waste Bag Integrity
- System and Subsystem Performance Testing
- Disposable Component Chemical Resistance Test

Biocompatibility

The following biocompatibility testing was performed to support the safety of the valve connectors:

- Cytotoxicity Study Using the ISO Elution Method
- Guinea Pig Maximization Sensitization Test
- Rabbit Intracutaneous Reactivity
- USP Rabbit Pyrogen Study
- Bacterial Reverse Mutation Study
- Genotoxicity: Mouse Lymphoma Assay
- Hemocompatibility Assay for Coagulation and Hematology Parameters
- ASTM Hemolysis Study
- ASTM Partial Thromboplastin Time
- SC5b-9 Complement Activation Assay
- Chemical Characterization
- Chronic Toxicity
- Carcinogenicity

Discussion of Verification and Validation

Verification and Validation Testing

Verification and Validation of the NxStage Cartridge Express with Speedswap was designed to verify and validate that it performs according to product specifications. The approved protocols included pass/fail criteria for each of the tests performed. Any new risk control measures identified in the Risk Management activities or usability requirements identified in the Usability Engineering file traced to requirements that were verified. All testing passed.

Human Factors Validation

The critical tasks associated with the new Speedswap features for the proposed cartridge and proposed kit were evaluated during Summative Evaluation (Human Factors Validation).
The Summative Evaluation results in conjunction with a post-evaluation risk analysis indicate

that the NxStage Cartridge Express with Speedswap and Express Speedswap kit are safe and effective for intended users, uses, and use environments.

Conclusion:

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 were conducted to characterize the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage Cartridge Express with Speedswap and Speedswap Kit is substantially equivalent to the predicate device and is suitable for the labeled indications for use.