March 14, 2024

NxStage Medical Inc.
Denise Oppermann
VP Regulatory Affairs North America
350 Merrimack Street
Lawrence, Massachusetts 01843

Re: K232803
Trade/Device Name: NxStage System One with Cartridge Express (CAR-170-E and CAR-172-E)
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: February 12, 2023
Received: February 12, 2023

Dear Denise Oppermann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gema Gonzalez -S

Maura Rooney, MS
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232803

Device Name
NxStage System One with Cartridge Express (CAR-170-E and CAR-172-E)

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 or chronic care facility. The NxStage System One is also indicated for hemodialysis with or without ultrafiltration in the home.
All treatments must be administered under 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.

1. 510(K) SUMMARY

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

1.1. Submitter's Information

Name:	NxStage Medical, Inc.
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Contact Person:	Denise Oppermann, Vice President
Preparation Date:	11 September 2023

1.2. Device Name

Trade Name:	NxStage System One with Cartridge Express (CAR-170-E and CAR-172-E)
Common Name:	Dialyzer, High Permeability with or without Sealed Dialysate System
Regulation Name:	High permeability hemodialysis system
Regulatory Class:	Class II per 21 CFR § 876.5860
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability with or without Sealed Dialysate System
FDA Review Panel:	Gastroenterology/Urology

1.3. Legally Marketed Predicate Device

The legally marketed predicate device is the NxStage System One with Cartridge Express cleared under K061837. This predicate has not been subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

The NxStage Cartridge Express is the subject of this 510(k) and is available in two (2) configurations as shown in Table 1.

Table 1: Model Numbers and Description

Description	Model Number
NxStage Cartridge Express	CAR-170-E
NxStage Cartridge Express with needleless access sites	CAR-172-E

1.4.2. Device Characteristics

The NxStage Cartridge is available with a pre-attached high permeability dialyzer, together referred to as the "NxStage Cartridge Express". The NxStage Cartridge Express is a gamma-sterilized, single-use device. The dialyzer is provided with the blood pathway sterile and non-pyrogenic.

1.4.3. Environment of Use

The NxStage Cartridge Express is used in environments where hemodialysis is performed.

1.4.4. Brief Written Description of the Device

The NxStage System One dialysis system consists of an electro-mechanical cycler and a disposable Cartridge Extracorporeal Blood and Fluid Circuit (NxStage Cartridge). The NxStage Cartridge is available with a pre-attached high permeability dialyzer, together referred to as the "NxStage Cartridge Express".

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.

The NxStage Cartridge Express filter is made up of a fiber bundle maintained within a polyethylene terephthalate glycol (PETG) dialyzer housing. The polysulfone fiber bundle is a semipermeable, hollow fiber membrane through which water molecules and smaller molecular weight solutes pass from the blood to the dialysate, but larger molecular weight solutes (such as proteins) do not. Uremic toxins and waste products are removed from the patient's blood by means of diffusion during hemodialysis.

1.4.5. Materials of Use

The NxStage Cartridge Express dialyzer is made up of a fiber bundle maintained within a PETG dialyzer housing. The fiber bundle located within the dialyzer housing is made of polysulfone.

1.4.6. Key Performance Specifications and Characteristics

Urea, Creatinine, and Vitamin B12 clearance are key performance indicators for dialyzers due to the variety of their molecule sizes. Molecules are used to exhibit movement across the membrane. Table 2 exhibits the clearance information provided in the instructions for use (IFU) for these molecules. Figure 1 provides ultrafiltration information.

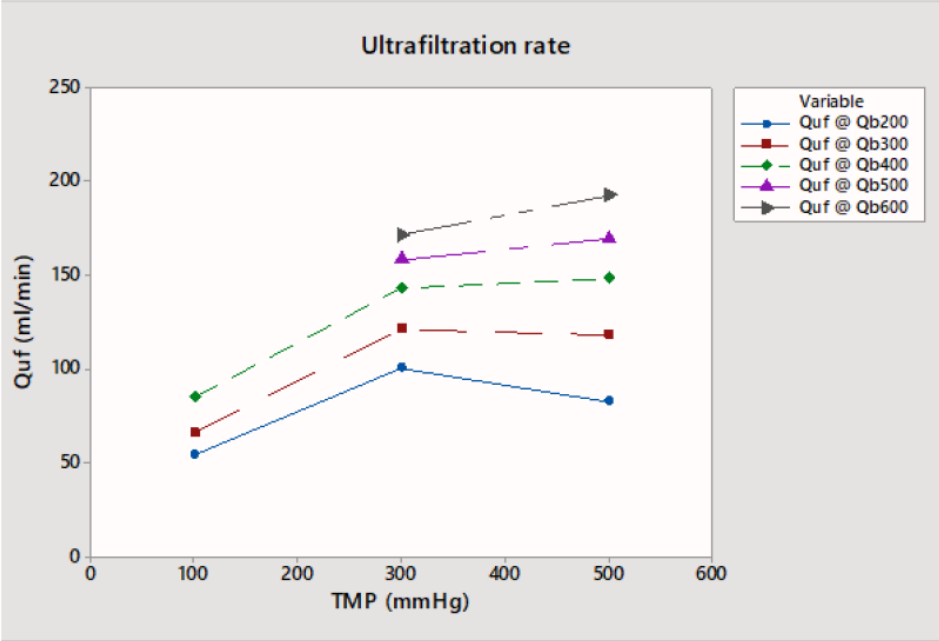
Table 2: *In vitro* Clearance Performance Data

Clearance in mL/min, Q_{UF}[1] = 0 mL/min					
Q_D[2] in mL/min	100	100	100	200	200
Q_B[3] in mL/min	200	300	400	400	500
Urea	100	100	100	195	199
Creatinine	97	100	99	182	186

Clearance in mL/min, Q_{UF}[1] = 0 mL/min					
Vitamin B_{12}	84	92	95	138	143

[1] Q_{UF} = Ultrafiltration rate
[2] Q_D = Dialysate flow rate
[3] Q_B = Blood flow rate

Figure 1: Ultrafiltration Rate



In Vitro Test Results with bovine blood. Inlet conditions: Hct. 32%; Total Protein 6 gm/dL; Temperature 37° C.

1.5. Intended Use

The NxStage System One and its related components is used to treat patients with renal insufficiency and/or fluid overload by delivering hemofiltration, hemodialysis, ultrafiltration, or a combination of hemofiltration/ultrafiltration or hemodialysis/ultrafiltration.

1.6. 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 or chronic care facility. The NxStage System One is also indicated for hemodialysis with or without ultrafiltration in the home.

All treatments must be administered under 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.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the proposed NxStage Cartridge Express remain unchanged when compared to the predicate device, the NxStage Cartridge Express cleared under K061837:

- Intended use including the same indications for use
- Fundamental Scientific Technology / Operating Principle
- Essential performance requirements
- Materials, aside from the alternate dialyzer fiber (subject of this submission)
- Sterilization method, packaging, and sterility label claims

1.8. Performance Data

Performance testing was conducted in accordance with ISO 8637-1 First Edition 2017-11 and *Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers, August 1998*. The following testing was conducted to support the determination of substantial equivalence:

- Performance testing – clearance testing, ultrafiltration performance and membrane performance
- Structural integrity testing – positive and negative pressure decay testing and blood compartment integrity (membrane integrity)

All testing met predetermined acceptance criteria and demonstrated that, like the predicate device, the NxStage Cartridge Express is safe and effective for its intended use.

1.8.1. Biocompatibility Testing

The following testing was performed in accordance with ISO 10993-1:2018 to support the biological safety of the dialyzer fiber change:

- Chemical analysis – extractables and leachables
- Cytotoxicity, ISO Neutral Red Uptake
- Sensitization, ISO Guinea Pig Maximization
- ISO Intracutaneous Irritation
- Systemic Toxicity (i.e., Acute Systemic Toxicity and Material Mediated Pyrogenicity)

- Hemocompatibility, ASTM Hemolysis (Direct and Indirect – Extract)
- Hemocompatibility, Complement Activation – SC5b-9
- Hemocompatibility, Platelet, WBC, RBC Counts
- Hemocompatibility, Mechanical Hemolysis
- Hemocompatibility, Thrombin-antithrombin III complex (TAT)

A toxicological risk assessment was also performed. No new biocompatibility concerns were raised as a result of using the alternate fiber discussed in this submission.

1.8.2. Human Factors Validation Testing

Not applicable. No Human Factors testing was required. The structural properties of the dialyzer and cartridge remain unchanged, and there is no change in how the device is set up or used. Therefore, there is no impact on usability.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The NxStage Cartridge Express does not have an electrical component.

1.8.4. Software Verification and Validation Testing

Not applicable. The NxStage Cartridge Express does not contain software.

1.8.5. Animal Studies

No animal studies were performed in support of the fiber change.

1.8.6. Clinical Studies

No clinical studies were performed in support of the fiber change.

1.9. Conclusion

The information provided in this submission demonstrates that the subject NxStage Cartridge Express functions as intended and supports the determination of substantial equivalence to the predicate device.

The results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns regarding safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance requirements of the NxStage Cartridge Express are substantially equivalent to those of the predicate device. NxStage Medical, Inc. concludes that within the meaning of the Medical Device Amendments Act of 1976, the NxStage Cartridge Express is safe and effective for its intended use.