January 18, 2024

NxStage Medical, Inc.
Caitlin Kalda
Senior Lead, Regulatory Affairs North America
350 Merrimack Street
Lawrence, Massachusetts 01843

Re: K233213
Trade/Device Name: NxStage PureFlow Solution
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: Class II
Product Code: KPO
Dated: December 19, 2023
Received: December 19, 2023

Dear Caitlin Kalda:

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)*
K233213

Device Name
NxStage PureFlow Solution

Indications for Use *(Describe)*
NxStage PureFlow Solution is indicated for use with NxStage renal replacement therapy systems that utilize sterile premixed dialysate during hemodialysis for chronic care patients.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 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.

5.1. Submitter's Information

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence MA 01843 USA
Phone:	(617) 831-3469
Fax:	(781) 699-9635
Contact Person:	Caitlin Kalda, Senior Lead
Preparation Date:	28 September 2023

5.2. Device Name

Trade Name:	NxStage PureFlow Solution
Common Name:	Premixed Dialysate
Regulation Name:	Hemodialysis Systems and Accessories
Regulatory Class:	Class II per 21 CFR § 876.5820
Product Code:	78 KPO
Product Code Name:	Dialysate Concentrate for Hemodialysis (Liquid of Powder)
FDA Review Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate for the proposed device is the NxStage PureFlow Solution, as cleared through K033386 (November 26, 2003). This predicate has not been subject to a design-related recall.

5.4. Device Description

5.4.1. Device Identification:

The NxStage PureFlow Solution is a family of premixed dialysate solution formulations which are sterile, non-pyrogenic, fully constituted dialysate solutions provided in 5L single use flexible bags.

Table 1: Device Identification

Catalog Number	Description
RFP-204-A* RFP-204-B* RFP-204-C*	5000mL, 40 Lactate, 1K

Table 1: Device Identification

RFP-205-A RFP-205-B RFP-205-C	5000mL, 35 Lactate, 3K
RFP-207-A RFP-207-B RFP-207-C	5000mL, 45 Lactate, 1K
RFP-209-A RFP-209-B RFP-209-C	5000mL, 45 Lactate, 2K
RFP-211-A RFP-211-B RFP-211-C	5000mL, 40 Lactate, 2K
RFP-220-A RFP-220-B RFP-220-C	5000mL, 40 Lactate, 2K
RFP-221-A RFP-221-B RFP-221-C	5000mL, 40 Lactate, 3K
RFP-222-A RFP-222-B RFP-222-C	5000mL, 45 Lactate, 3K
RFP-223-A RFP-223-B RFP-223-C	5000mL, 35 Lactate, 2K
RFP-224-A RFP-224-B RFP-224-C	5000mL, 35 Lactate, 4K

* suffix of A, B, or C indicates country or region specific labeling content and language translations for the same dialysate formulation.

5.4.2. Device Characteristics

The NxStage PureFlow Solution is a sterile, nonpyrogenic, single-use device provided in a single chamber flexible bag. The device is sterilized using moist steam sterilization and SAL=10^{-6} using a validated sterilization cycle per ISO 17665-1:2006/(R)2013, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*

5.4.3. Environment of Use

The intended environments of use are:

- Dialysis Clinics
- Health Care Facilities
- Home
- Community at Large (e.g. travel/hotel)

5.4.4. Brief Written Description of the Device

The NxStage PureFlow Solution is a product family of fully constituted, sterile, non-pyrogenic dialysate solutions that are provided in single use, single chamber 5L flexible bags. The solutions are intended for use with renal replacement therapy systems that utilize sterile premixed dialysate.

A range of formulations is offered which allows the physician to prescribe the electrolyte compositions that meet the specific needs of individual patients. The solutions are not designed for use with proportioning hemodialysis systems and are not intended for direct infusion into the patient.

5.4.5. Materials of Use

Table 2: Materials

Where Used	Materials
Dialysate Fluid	Sodium chloride
	Potassium chloride dihydrate
	Calcium chloride dihydrate
	Magnesium chloride hexahydrate
	Sodium lactate
	Dextrose monohydrate
	Hydrochloric acid
	Water for injection
Container Materials	Polypropylene (PP)
	Styrene ethylene butylene styrene (SEBS)
	Styrene-isoprene-rubber (SIS)
	Polycarbonate (PC)

Duration and type of contact:

- Per ISO 10993-1 NxStage PureFlow Solution is categorized as:
  - External communicating device
  - Blood path, indirect
  - Long term (>30 d)

5.4.6. Key Performance Specifications/Characteristic

The NxStage PureFlow Solution is used as dialysate during hemodialysis therapy.

5.5. Intended Use

The NxStage PureFlow Solution is intended for use with renal replacement therapy systems that utilize sterile premixed dialysate. The solutions are not designed for use with intermittent proportioning hemodialysis systems. The NxStage offering of premixed dialysate solutions allows the physician to prescribe different electrolyte compositions that meet the specific needs of individual patients.

5.6. Indications for Use

NxStage PureFlow Solution is indicated for use with NxStage renal replacement therapy systems that utilize sterile premixed dialysate during hemodialysis for chronic care patients.

5.7. Comparison of Technological Characteristics with the Predicate Device

The proposed device has the same intended use, technological characteristics, and principle of operation as the predicate. The proposed device is similar in container design and configuration as compared to the predicate device and has similar performance specifications.

5.8. Performance Data

Performance testing has been conducted to support the determination of substantial equivalence with regards to design, safety, and efficacy. The testing is summarized in Table 3.

Table 3: Performance Testing Summary

Test Conducted	Test Method Description
Analytical testing	Per device specifications and applicable sections of USP and EP
Physical testing of container (bag)	Per device specifications
Container closure integrity testing	Per ISO 11607-1
Temperature excursion testing	Per device specifications
Stability/Shelf-life testing	Per ICH Q1A to support 24-month shelf life
Ship testing	Per ASTM D4169-22

5.8.1. Biocompatibility Testing

The NxStage PureFlow Solution has been evaluated for biological safety in accordance with ISO 10993 -1 and the FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process",* published Sept 4, 2020. The following testing was performed:

- Chemical characterization
- Toxicological Risk Assessment
- Cytotoxicity
- Sensitization
- Irritation
- Pyrogenicity
- Hemocompatibility
- Systemic toxicity

5.8.2. Human Factors Validation Testing

The NxStage PureFlow Solution is found to be safe and effective for its intended user, use, and use environments in accordance with the FDA guidance document "*Applying Human Factors and Usability Engineering to Medical Devices (*Feb 3, 2016) and applicable sections of AAMI/ANSI/IEC 62366-1.

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not Applicable – The device subject of this submission does not have any electronic features

5.8.4. Software Verification and Validation Testing

Not Applicable – The device subject of this submission does not have any software features.

5.8.5. Animal Studies

Not Applicable – The device subject of this submission did not use any animal studies

5.8.6. Clinical Studies

Not Applicable – The device subject of this submission did not require clinical studies

5.9. 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 was conducted to characterize the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage PureFlow Solution is suitable for the labeled indications for use.

The proposed modifications to the NxStage PureFlow Solution are substantially equivalent to the predicate device with regards to design, intended use, principle of operation and materials of construction. Differences between the proposed device and the predicate device do not introduce any new concerns regarding the safety of efficacy of the device. NxStage Medical, Inc. concludes that within the meaning of the Medical Device Amendments Act of 1976, the NxStage PureFlow Solution product family is safe and effective for its intended use.