May 15, 2026

Fresenius Medical Care Renal Therapies Group, LLC
Caitlin Kalda
Senior Lead Regulatory Affairs - Home
920 Winter St
Waltham, Massachusetts 02451

Re: K252377
Trade/Device Name: NxStage System One with NxView
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: April 14, 2026
Received: April 14, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MAURA ROONEY -S

Maura Rooney
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)*
K252377

Device Name
NxStage System One with NxView

Indications for Use *(Describe)*

NxStage System One

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 Therapeutic Plasma Exchange in a clinical environment.

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.

NxView

NxView is a computer-based touch screen user interface that provides online instructions for use, summarized system information and remote access.

NxView is contraindicated as the sole method of monitoring a patient during treatment.

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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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:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(857) 291-0009
Fax:	(781) 699-9635
Contact Person:	Caitlin Kalda, Senior Lead Regulatory Affairs – Home
Preparation Date:	19 August 2025

1.2. Device Name

Trade Name:	NxStage System One with NxView
Common Name:	Hemodialysis 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 NxStage System One with NxView (K133547) is the legally marketed predicate device. This predicate has not been subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

The NxStage System One comprises:

- NxStage Cycler – An electromechanical control unit
- 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
- NxView – A flat panel touch screen interface which is mounted on top of the cycler and provides online instructions for use, summarized system information, and remote viewing of treatment information

- TherapyWise is an optional feature to NxView that gives the user visual access to aggregated performance data of their account's Renal/Kidney Replacement Therapy (RRT/KRT) program to understand how the program is running and to identify areas for improvement (i.e., staff education, competency, and proficiency)

1.4.2. Device Characteristics

The NxStage System One cycler is an electromechanical control unit.

NxView is a communication device that captures, stores, and displays treatment information, and device labeling instructions. It does not input or control the NxStage Cycler.

TherapyWise, an optional feature to NxView, is a secure, web-based quality analytics tool that collects data from the NxStage System One with NxView system.

1.4.3. Environment of Use

The NxStage System One with NxView is designed to deliver hemofiltration, hemodialysis, and/or ultrafiltration in an acute or chronic care facility. The NxStage System One with NxView is also indicated for Therapeutic Plasma Exchange in a clinical environment.

1.4.4. Brief Written Description of the Device

This submission is for a NxStage System One with NxView (also referred to as "NxView") software update. The device's operating principles and hardware remain unchanged.

NxView is a computer-based touch screen interface that provides online instructions for use, graphical trend analyses, summarized system information, and stores treatment log files. It does not input or control the NxStage System One Cycler. The additional information provided on NxView can be beneficial for an operator of longer treatments, as well as for training a new operator. NxView also provides remote viewing of treatment information using a network connection.

The key features of NxView include:

- Real-time summary of therapy progress
- Access to online operating instructions
- System alarms notification and context-sensitive help
- History and event log to facilitate charting
- Graphical tools to enable trend analysis

TherapyWise is an optional, secure, web-based quality analytics tool that collects data from the NxStage System One Critical Care system via NxView.

TherapyWise provides the following functions:

- Captures performance data from NxView
- Sends performance data to a central secure location

- Formats the data into a user-friendly dashboard for secure presentation through a supported web browser
- Provides access for clinicians to view dashboard remotely via a secure web interface
- Allows remote viewing and the configuration of NxView settings such as phone numbers, font sizes, and chimes (sounds). (Note: Only the sounds can be changed. The sounds are not able to be muted, nor is the volume able to be changed from TherapyWise.)

1.4.5. Materials of Use

The NxView touch screen materials are listed in Table 1.

1.4.6. Key Performance Specifications/Characteristics

The NxStage System One with NxView hardware is not changing; therefore, the performance specifications remain the same as the predicate device. The part numbers listed in Table 1 are the currently marketed NxView monitors on which the TherapyWise software will be supported.

Table 1: Performance Specification Summary

Category	Item Name	NX1274 (-A)[1]	NX3302-A
NxStage Product Name	Product Name	ASSY, NxView TOUCH MONITOR, TESTED AND PACKAGED	ASSY, MTP-1233 TOUCH MONITOR, TESTED AND PACKAGED, ROHS
Power	Power Input	+12 to +26V DC Input ± 10%	+12V to +26V DC input
	Power Output	N/A	N/A
Physical Characteristics	Dimensions	260 x 310 x 51 (mm)	260 x 310 x 51 (mm)
	Weight	2.3 kg	2.3 kg
CPU and Memory	Processor	Intel® Atom™ processor D525 1.8GHz Processor	Onboard Intel® Pentium® Processor N4200
	Chipset	Integrated	Intel Apollo Lake SoC integrated
	Memory	1GB Onboard DDR3 Memory 1 x 2GB DDR3 SODIMM (Innodisk M3S0-2GHJCCN9 or M3S0-2GSJCCN9) Total 3GB DDR3 Memory	1 x 204-pin DDR3L 1866MTs SO-DIMM 4 GB
Display and Touch Screen Technology	LCD Panel	12.1” 1024x768 TFT-LCD	12.1" XGA TFT LED PANEL CMO G121X1-L03; 1024 x 768 pixels
	Touch Screen	5-wire Resistive Touch Screen	Touch panel 5 wire Analog RoHS; T121S-5RB014N-0A18R0-200FH

Table 1: Performance Specification Summary

Category	Item Name	NX1274 (-A)[1]	NX3302-A
	Touch Controller	N/A	USB touch (EETI)
I/O Ports	Serial Port	1st: DB9 RS-232 2nd: DB9 RS-232 (replaces Compact Flash on standard MTP-1205)	2 x RS-232/422/485
	USB	2 x USB 2.0 (bottom access) 2 x USB 2.0 (side access)	Side USB 2.0 x 2 Ports Rear USB 3.0 x 4 Ports
	Audio	1 x Line-Out 2 x 2W Speakers	1 x Line-Out 2x 2W speakers
	LAN	N/A	2 x RJ-45
	Wireless LAN Antenna	2 x Internal Wi-Fi Antenna	PCB Antenna 2.4/5.0GHz-IPEX Ø1.13mm 50cm x 2
	Other	1 x DB15 VGA port	1 x HDMI
Shipping	Box Shipping	NC5299 BOX, SHIPPING, 17.75 X 11.38 X 15.88, 350LB BC KRAFT with shipping foam	NC5299 BOX, SHIPPING, 17.75 X 11.38 X 15.88, 350LB BC KRAFT with shipping foam

[1] Note: The NX1274 and NX1274-A are identical except that NX1274-A is RoHS compliant.

1.5. Intended Use

The NxStage System One with NxView is designed to deliver hemofiltration, hemodialysis, and/or ultrafiltration in an acute or chronic care facility. The NxStage System One with NxView is also indicated for Therapeutic Plasma Exchange in a clinical environment.

1.6. Indications for Use

The indications for use remain the same as the predicate device (K133547).

NxStage System One

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 Therapeutic Plasma Exchange in a clinical environment.

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.

NxView

NxView is a computer-based touch screen user interface that provides online instructions for use, summarized system information and remote access.

NxView is contraindicated as the sole method of monitoring a patient during treatment.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the NxStage System One with NxView are substantially equivalent to those of the predicate system (K133547):

- Intended Use/Indications for Use
- Design Specifications
- Technological Characteristics
- Principle of Operation
- Performance Requirements

The proposed device differs from the predicate device regarding the following modifications:

- Software changes

Verification testing was performed to verify the safety and effectiveness of the proposed device for its intended use. Differences between the predicate and proposed device do not raise any questions of safety or effectiveness.

1.8. Performance Data

The following performance tests were conducted on the NxStage System One with NxView to support the determination of substantial equivalence:

- Software Verification and Validation

1.8.1. Biocompatibility Testing

Not applicable. No biocompatibility testing was required because the change is software only.

1.8.2. Human Factors Validation Testing

Not applicable. Based on the use-based risk analyses, no critical tasks are associated with the use of NxView and TherapyWise. Therefore, Human Factors Testing was not required.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. No EMC or wireless technology information is needed because the change is software only.

1.8.4. Software Verification and Validation Testing

Software verification testing was performed to demonstrate the efficacy of the software. The following testing was performed:

- Functional and Performance Verification
- Regression Testing

Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- *Content of Premarket Submissions for Device Software Functions (14 June 2023)*
- *Off-The-Shelf Software Use in Medical Devices (11 August 2023)*
- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (27 June 2025)*

1.8.5. Animal Studies

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

1.8.6. Clinical Studies

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

1.9. Conclusions

The indications for use, design, principle of operation, and technological characteristics of the NxStage System One with NxView are substantially equivalent to those of the predicate device. Test results demonstrate that the differences between the NxStage System One with NxView and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that with the meaning of the Medical Device Amendments Act of 1976, the NxStage System One with NxView is safe and effective for its intended use.