August 11, 2023

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

Re: K230632
Trade/Device Name: VersiHD with GuideMe software
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: July 14, 2023
Received: July 14, 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 (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,

Anil K. Kochhar -S

Acting for:
Gema Gonzalez
Acting 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)*
K230632

Device Name
VersiHD with GuideMe Software

Indications for Use *(Describe)*
The NxStage system 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 and solo home hemodialysis during waking hours.

All treatments must be administered under a 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.

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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.
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Contact Person:	Denise Oppermann, VP Regulatory Affairs North America
Preparation Date:	March 2, 2023

5.2. Device Name

Trade Name:	VersiHD with GuideMe Software
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

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the NxStage System One Plus cleared under K170469. This predicate has not been subject to a design-related recall.

5.4. Device Description

The VersiHD with GuideMe Software is comprised of the NxStage Cycler, an electromechanical control unit and the NxStage Cartridge (disposable) 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. It is also indicated for home

hemodialysis, including home nocturnal hemodialysis and solo home hemodialysis during waking hours.

5.4.1. Device Identification

The Model Numbers for subject to this submission are listed in Table 1.

Table 1. VersiHD with GuideMe Software Model Numbers and Description

Model Number	Description
NX1000-10-E	VersiHD with GuideMe software

VersiHD units that get serviced will be assigned NX1000-10-F or NX1000-16-F when upgraded to include VersiHD with GuideMe Software.

5.4.2. Device Characteristics

The VersiHD with GuideMe Software system is software driven, consisting of the cycler (machine) and a Cartridge (disposable). Depending on the use environment and materials used with the system, the VersiHD is able to perform a variety of renal therapy types as required by the health care provider including nocturnal and solo dialysis.

5.4.3. Environment of Use

The intended environments are Dialysis center or Dialysis Clinic (health care facility), Home, and Community at Large (such as Travel Use (e.g. Hotel)).

5.4.4. Brief Written Description of the Device

The VersiHD with GuideMe Software includes a cycler and disposable NxStage Cartridge. The system components are described in Table 2.

Table 2. VersiHD with GuideMe Software Components Description

Component	Description
Control Panel	All user inputs and informational readouts are communicated via the control panel

Pumps	The NxStage Cycler houses four peristaltic pumps: the blood pump, ultrafiltration pump, waste fluid pump and therapy fluid pump
Balance Chambers	Volumetric fluid management is controlled by the balance chamber subsystem, which ensures that the volume of waste fluid removed from the patient is equivalent to the volume of sterile replacement fluid infused into the patient for hemofiltration; or ensures flow rate and volume control of dialysate in hemodialysis.
Pressure Transducers	Electronic pressure transducers monitor the pressures in the Cartridge blood and fluid pathways.
Pinch Clamp Actuators	Solenoid and cam-driven pinch clamp actuators control the flow of blood and fluids in the Cartridge.
Air Detection Sensor	An ultrasonic air detector monitors for air in the venous blood return line.
Blood Leak Detector	An optical blood leak sensor monitors for blood in the waste fluid pathway.
Fluid Temperature Sensor	An additional, redundant safety feature which monitors the dialysate fluid temperature.
Software	There are two separate microprocessors: the Control Processor and the Safety Processor. The two processors communicate with each other via the Serial Communications Interface. The Control Processor controls the functions of the Cycler. The Safety Processor monitors the Cycler, creates alarms, and alerts when necessary

The Cycler is an electro-mechanical device that interfaces with the NxStage Cartridge. The NxStage Cycler performs the following functions:

- Loads and primes the NxStage Cartridge and filter
- Performs pressure tests and alarms tests

- Pumps blood from the patient, through the filter, and returns the filtered blood to the patient.
- Controls net fluid removal from the patient (ultrafiltration)
- Balances the removal of waste fluid with the infusion of sterile replacement fluid (hemofiltration).
- Balances and maintains the dialysate flow (hemodialysis)
- Monitors critical operating parameters relating to patient safety. It also monitors treatment parameters and alerts the operator for possible intervention.
- Rinses back blood to the patient at the conclusion of treatment.

5.4.5. Key Performance Specifications/Characteristic

The VersiHD with GuideMe Software performance requirements are provided in Table 3.

Table 3. VersiHD with GuideMe Software performance requirements

Feature	Specification
Technology / Components:	
Hemodialysis **Hemofiltration** **Ultrafiltration**	Yes Yes Yes
Pumps	4 peristaltic pumps
Valves (clamps)	2 solenoid actuated pinch clamps 8 cam driven pinch clamps
Air / fluid detectors	3 ultrasonic air/ fluid detectors
Blood leak detector	1 optical blood leak detector
Pressure transducers	5 electronic pressure transducers
Flow Rates:	

Feature	Specification
Blood	10-600 ml/min
Prescription Fluid /Dialysate Flow	0-18000 ml/hr
Ultrafiltration	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Yes
Venous Pressure Monitor	0 to 400 mmHg
IV Prescription Fluid	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436, K060296, K080919, K111174 & K140571)
Compatible Blood Tubing Set	NxStage Standard Cartridge
User Interface	Touch Screen
Alarms	75 dB
Software	VersiHD with GuideMe Software version 2.0

5.5. Intended Use

The VersiHD with GuideMe software is intended 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 intended for hemodialysis with or without ultrafiltration in the home.

5.6. Indications for Use

The NxStage system 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 and solo home hemodialysis during waking hours.

All treatments must be administered under a 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.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the VersiHD with GuideMe Software remain unchanged when compared to the predicate device, NxStage System One Plus (K170469).

- Intended Use
- Fundamental Scientific Technology/Operating Principle
- Energy Source
- Materials
- Essential Performance Requirements

The VersiHD with GuideMe Software is a software only modification to the current, in market, VersiHD cycler's graphical user interface (GUI) touch screen. The VersiHD with GuideMe Software is utilizing a new optional "Guide Me" feature in which step-by-step instructions are available for users if they press the "Guide Me" button on the updated user interface .

5.8. Performance Data

Testing conducted to support the determination of substantial equivalence is summarized in Table 4.

Table 4. Performance Testing Summary

Test Conducted	Test Method Description
Simulated Treatments (Intended Users, Uses and Use Environment)	Simulated home hemodialysis treatments were performed in a simulated use environment (dialysis center/clinic or home setting).
Software V&V	Software requirements were verified according to pre-determined performance specifications.
System V&V	System requirements were verified according to pre-determined performance specifications.

Test Conducted	Test Method Description
Basic Safety and Essential Performance	Complies with IEC 60601-1 standards and IEC 60601-2-16

5.8.1. Human Factors Validation Testing

The VersiHD with GuideMe Software was validated for safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (February 3, 2016).

5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)

Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2:2014 (4th Edition). Note: The IEC 60601-1-2:2007 (3rd Edition), Model NX1000-16-F and NX1000-10-F (4th edition), serviced cyclers will be upgraded with the VersiHD with GuideMe Software. Electromagnetic Compatibility information within this submission is provided in accordance with FDA guidance document *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices* (11 July 2016).

5.8.3. Software Verification and Validation Testing

Unit, software, regression (system verification), and validation testing were performed to demonstrate the effectiveness of the software and to confirm operation of the machine. Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (11 May 2005)
- *Content of Premarket Submissions for Management of Cybersecurity in Medical device* (02 October 2014)

5.8.4. Animal Studies

N/A. No animal studies were conducted.

5.8.5. Clinical Studies

N/A. No clinical studies were conducted.

5.9. Conclusion

The information provided in this submission demonstrates the VersiHD with GuideMe Software functions as intended and supports the determination of substantial equivalence to the predicate device.

Test results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns with regard to safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance requirements of the VersiHD with GuideMe Software 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 VersiHD with GuideMe Software is safe and effective for the intended use.