



Food and Drug Administration
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August 24, 2017

NxStage Medical, Inc.
Heather V. Nigro, MS, RAC
Vice President, Regulatory and Clinical Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K171331
Trade/Device Name: NxStage[®] System One
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: July 31, 2017
Received: August 1, 2017

Dear Heather V. Nigro:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Glenn B. Bell -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K171331**

Device Name: NxStage® System One

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 System is also indicated for home hemodialysis, including home nocturnal hemodialysis and solo home hemodialysis during waking hours.

All treatments must be administered under 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

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 Prepared: May 05, 2017

Submitter's Information:

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**FDA Establishment
Owner/Operator Number:** 9045797

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Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

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Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	78 KDI

Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

Comparison to Predicate:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K150472 (June 04, 2015) and was found to be substantially equivalent.

Device Description:

The NxStage System One is comprised of the NxStage Cyclor, an electromechanical control unit; the 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 Cyclor. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

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 System is also indicated for home hemodialysis, including home nocturnal hemodialysis and solo home hemodialysis during waking hours.

All treatments must be administered under 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.

Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar components and features also used in the predicate device.

Summary of Performance Testing – Clinical

NxStage conducted a survey to obtain Patient Preference Information (PPI) of current HHD patients' willingness to perform Solo HHD during waking hours given the risks and benefits as compared to In-Center Hemodialysis. The survey was designed to identify thresholds of risk tolerance as well as obtain direct PPI regarding access to Solo HHD therapy. Survey results were used to support this regulatory submission for the indication expansion to include Solo HHD during waking hours, and this PPI was used to inform the updates made to the labeling.

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Current HHD patients were contacted via email by a third-party vendor using unbranded communication and invited to respond to an online survey about home hemodialysis. Each patient was provided a unique link for the survey to ensure that responses were not duplicated. Patients were offered compensation for completing the survey. The survey response period was left open for an amount of time determined to be sufficient to garner responses from the majority of those willing to respond, as confirmed with metrics tracked by the vendor.

A total of 1049 patients from 129 dialysis centers were contacted electronically to participate in the survey. Qualifying patients responded at a rate of 13.5% for a total of 142 evaluable responses. All dialysis centers and patients were located in the United States of America.

Twenty-two (15%) patients reported that they were current Solo HHD patients at the time of being surveyed. Responses to the threshold technique questions for these patients were evaluated separately from those currently performing HHD or in-center self-care hemodialysis with a care partner.

Patients who met the inclusion/exclusion criteria were considered experienced patients, having completed training and begun performing HHD treatments at the time of being surveyed.

Respondents were 70% male, 53% younger than 60 years old, generally equally geographically spread across the United States regions (20% Northeast, 23% South, 35% Midwest, 22% West), 31% employed either full or part-time, 78% white/Caucasian, 16.9% black and 9% Hispanic. Additionally, ages groups <20 and >90 were not represented in the data set.

Using the Threshold Technique, we asked current HHD patients to review scenarios presenting fixed benefit-risk profiles of In-Center HD and Solo HHD with variable risk of death or needle dislodgement. Patients were then asked whether they would choose In-Center HD or Solo HHD for the given scenario. These Threshold Technique questions were used to identify their risk tolerance thresholds with respect to the potentially increased risks of death and needle dislodgement associated with Solo use.

These questions showed that 55% of patients with less than one year of home or in-center self-care hemodialysis experience and 49% of patients with at least one year of experience would choose Solo use if the risk of death was 30% (compared to 16%, the estimated current risk of death with in-center hemodialysis). The following table presents the percentage of patients who would choose Solo HHD for each threshold interval of mortality risk presented in the survey.

Threshold Interval*	N (%)
≤16%	135 (95%)
>16% to 20%	120 (85%)
>20% to 25%	97 (68%)
>25% to 30%	71 (50%)
>30% to 35%	56 (39%)

*Threshold Interval of mortality risk in which the choice of respondents shifted from Solo HHD to In-Center HD, indicating both are of equivalent values to them.

With regard to the risk of needle dislodgement leading to serious injury, 65% of patients with less than one year of experience and 53% of patients with at least one year of experience selected Solo HHD instead of In-Center HD in the scenario where the event occurred in 11% of all treatments (compared to 0.2%, the reported risk of catastrophic needle dislodgement in HHD with a care

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partner present as described by Wong et al (0.2%)¹). The following table presents the percentage of patients who would choose Solo HHD for each threshold interval of needle dislodgement risk presented in the survey.

Threshold Interval*	N (%)
≤0.7%	125 (88%)
>0.7% to 2%	107 (75%)
>2% to 11%	79 (56%)
>11% to 33%	51 (36%)
>33% to 67%	36 (25%)
>67% to 100%	27 (19%)

*Threshold Interval of risk of needle dislodgement in which the choice of respondents shifted from Solo HHD to In-Center HD, indicating both are of equivalent values to them.

Patients were stratified into two HHD use vintages: less than 1 year of experience (N=31); 1 or more years of experience (N=111). Patients were similarly likely to choose Solo HHD in both groups (direct preference: 48% vs. 52%, respectively) with an additional 16% and 15% already doing Solo HHD in each respective patient vintage group. When further stratified into more specific HHD vintages, the only respondent group showing a difference in preference for Solo HHD was those with three or more years of HHD experience, who had a significantly higher proportion of patients selecting Solo HHD (72%).

Patients who would choose Solo HHD instead of In-Center Hemodialysis when faced with not having a partner were more likely to be under 60 years old and non-diabetic. These patients were also more likely to feel comfortable with doing a treatment without help either during training or immediately following transition home. Those who would choose Solo HHD were not as concerned about the potential for increased risks and thus have a higher risk tolerance threshold for death or needle dislodgement. These patients are more confident that they could perform the treatment steps alone and handle any issues that arise during treatment. They were also more likely to currently address hypotensive events without partner assistance, and were more likely to have done an entire treatment without their partner present in the most recent three months. Patients who would choose Solo HHD find the benefits of home hemodialysis to be extremely valuable, and in particular reported they typically want more flexibility with treatment length and place a higher value on the increased likelihood of receiving a transplant while on HHD. Importantly, patients choosing Solo HHD were much more likely to report they do not have limitations that would prevent them from doing the therapy.

Based upon the PPI obtained, results of the survey have provided demonstrable evidence of risk thresholds that patients are willing to tolerate if provided Solo HHD as a therapy option. Additionally, PPI indicated a desire for access to a Solo HHD indication for use. This PPI data is specific to patients using the NxStage System One. The NxStage System One for Solo HHD is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

Summary of Non-Clinical Test/Performance Testing - Bench

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

¹ Wong B, Zimmerman D, Reintjes F, Courtney M, Klarenbach S, Dowling G, Pauly RP. Procedure-related serious adverse events among home hemodialysis patients: a quality assurance perspective. Am J Kidney Dis. 2014 Feb;63(2):251-8. doi: 10.1053/j.ajkd.2013.07.009. Review. PubMed PMID: 23993152.

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indications for use. Verification and validation testing was conducted to characterize the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.