NxStage Medical, Inc.
NxStage Connected Health System
510(k) Premarket Notification

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

A.	**Date**	September 9, 2013
B.	**Submitter's Information:**	
	Name:	NxStage Medical, Inc.
	Address:	350 Merrimack Street Lawrence, MA 01843 United States
	FDA Establishment Owner/Operator Number:	9045797
	Contact Person:	Mary Lou Stroumbos Regulatory Affairs Manager
	Phone: **Fax:**	(978) 687-4872 (978) 687-4750
	Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843 United States
	FDA Establishment Registration Number:	3003464075
	Sterilization Site:	Not Applicable

OCT 10 2013

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C. Device Name:

Trade/Proprietary Name:	NxStage Connected Health System
Common/Usual Name:	Accessory to Hemodialysis Delivery System; e-Health Device
Classification Name:	Hemodialysis System and Accessories
Regulation Number:	21 CFR 876.5820
Product Code:	78 FKP – System, dialysate delivery, single patient
Device Classification:	Class II
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

C. Predicate Devices:

BL Healthcare TCx-I-DV Remote Care Management System K093379

D. Substantial Equivalence:
The NxStage Connected Health device is substantially equivalent in design, function and operation to the identified predicate.

E. Device Description/Indications for Use:

Device Description:
The NxStage Connected Health system collects, stores, and transmits medical information such as flowsheet data, vital signs, blood pressure, weight, and dialysis data from the patients on the completion of their dialysis treatment and transmits these results to their healthcare practitioner at another facility. The system also provides online labeling, treatment status, trending and supports education and messaging.

The internet server receives the patient data from the home setting or remote location where it is made available to the healthcare facility to track, graph, trend, note variances, set alert criteria, and receive alerts when parameters are outside the criteria set.

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Indications for Use:

The NxStage Connected Health System is for use by chronic hemodialysis patients remotely in combination with the NxStage System One and a variety of devices such as blood pressure monitor and weight scale upon the prescription of a licensed physician or healthcare practitioner. The Connected Health System serves as the data repository and communication link to the server software which is utilized by the healthcare facility. The healthcare facility may include the physician or licensed healthcare practitioner, other clinicians, or a disease management center.

The purpose of the system is to collect, accumulate, store and transmit medical information such as flowsheet data, vital signs, blood pressure, weight and dialysis data from the patient on the completion of their dialysis treatment and transmit these results to their healthcare practitioner at another facility. The system also provides online labeling, treatment status, trending and supports education and messaging.

The device is not intended to provide time sensitive data or alarms and does not control the System One Cycler. This system may not be used as a substitute for direct medical intervention or emergency care.

Interpretation of the information collected and transmitted requires clinical judgment by an experienced medical professional.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as the predicate device. Refer to Table 1 for a device comparison.

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INDICATIONS FOR USE CONT.	The device is not intended to provide time sensitive data or alarms and does not control the System One Cycler. This system may not be used as a substitute for direct medical intervention or emergency care. Interpretation of the information collected and transmitted requires clinical judgment by an experienced medical professional.	The system is installed by or with support from trained professionals. The device is not intended to provide time sensitive data or alarms. This system may not be used as a substitute for direct medical intervention or emergency care. Interpretation of the information collected and transmitted requires clinical judgment by an experienced medical professional.
INTENDED USE	Accessory to Hemodialysis Delivery System; e-Health Device	Telemedicine System
INTENDED USERS	Home Users, Healthcare Practitioners	Home Users
SITE OF USE	Home, Clinic	Home, Clinic
DATA COLLECTION SOFTWARE	Proprietary Software	Proprietary Software
COMMUNICATION METHOD WITH DEVICES	Secure Wi-Fi Connection	Wireless RF Protocol
COMMUNICATION METHOD WITH REMOTE CARE MANAGEMENT SYS.	Secure Broadband Internet Connection	Secure Broadband Internet Connection

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G. Summary of Non-Clinical Test/Performance Testing - Bench

The information and data provided in this submission clearly describe the proposed device and demonstrate that the device is adequately designed for the labeled indications for use and substantially equivalent to predicate device. Performance, verification and validation testing was conducted to characterize performance of the proposed device. This included testing for software readiness, software design review, and usability.

All predetermined acceptance criteria were met. Results of this testing also document that the proposed NxStage Connected Health System is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

NxStage Medical, Inc.
% Mary Lou Stroumbos
Regulatory Affairs Manager
350 Merrimack Street
Lawrence, MA 01843

Re: K131739
Trade/Device Name: NxStage Connected Health System
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FKP
Dated: September 9, 2013
Received: September 10, 2013

Dear Mary Lou Stroumbos,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Glenn B. Bell -S

Acting 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): K131739

Device Name: NxStage Connected Health System

Indications for Use: The NxStage Connected Health System is for use by chronic hemodialysis patients remotely in combination with the NxStage System One and a variety of devices such as blood pressure monitor and weight scale upon the prescription of a licensed physician or healthcare practitioner. The Connected Health System serves as the data repository and communication link to the server software which is utilized by the healthcare facility. The healthcare facility may include the physician or licensed healthcare practitioner, other clinicians, or a disease management center.

The purpose of the system is to collect, accumulate, store and transmit medical information such as flowsheet data, vital signs, blood pressure, weight and dialysis data from the patient on the completion of their dialysis treatment and transmit these results to their healthcare practitioner at another facility. The system also provides online labeling, treatment status, trending and supports education and messaging.

The device is not intended to provide time sensitive data or alarms and does not control the System One Cycler. This system may not be used as a substitute for direct medical intervention or emergency care.

Interpretation of the information collected and transmitted requires clinical judgment by an experienced medical professional.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Glenn B Bell -S