WellDoc, Incorporated
Danielle Dorfman
Manager, Regulatory Affairs and Quality System
10221 Wincopin Circle Suite 150
Columbia, Maryland 21044

May 17, 2024

Re: K162225
Trade/Device Name: WellDoc BlueStar (WellDoc DiabetesManager® System and DiabetesManager®-Rx System)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MRZ, NDC

Dear Danielle Dorfman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 22, 2016. Specifically, FDA is updating this SE letter as an administrative correction. A secondary product code, LNX, was inadvertently included.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Juliane Lessard, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6126, Juliane.Lessard@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery,
General Hospital and Human Factors Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

November 22, 2016

WellDoc, Incorporated
Danielle Dorfman
Manager, Regulatory Affairs and Quality System
10221 Wincopin Circle, Suite 150
Columbia, Maryland 21044

Re: K162225
Trade/Device Name: WellDoc Bluestar (WellDoc DiabetesManager® System and DiabetesManager®-Rx System)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, LNX, NDC
Dated: October 26, 2016
Received: October 27, 2016

Dear Danielle Dorfman:

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 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 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162225

Device Name

WellDoc Bluestar (WellDoc DiabetesManager® System and DiabetesManager®-Rx System)

Indications for Use *(Describe)*

DiabetesManager® (OTC Use): The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older -who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

DiabetesManager®-Rx (Prescription Use): The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have type 2 diabetes. The DiabetesManager®-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager®-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or 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.

510(k) Summary

K162225

General Information

Date of Summary Preparation: November 18, 2016

Name of Manufacturer:	WellDoc, Inc.
Address:	10221 Wincopin Circle Suite 150 Columbia, MD 21044
Contact Person:	Kevin McRaith Chief Executive Officer
Phone:	(443) 692-3100
Fax:	(443) 692-3099
Trade or Proprietary Name:	WellDoc BlueStar (DiabetesManager® System and Diabetes Manager®-Rx System)
Common or Usual Name:	Medical computers and software Infusion pump accessories
Product Codes:	LNX, MRZ, NDC
Classification Name:	LNX is unclassified and therefore has no regulation number 21 CFR 880.5725 (Infusion Pump)
Regulatory Class:	II

Classification Panel: General Hospital

Predicate Device: K100066 (WellDoc DiabetesManager® System and Diabetes Manager®-Rx System)

Device Description

The WellDoc BlueStar DiabetesManager® System is a stand-alone, over-the-counter (OTC) software system that has the capability of providing additional functions, if and when, the functions are prescribed by the prescribing healthcare provider. Once the additional prescription (Rx) functions are activated, the entire software system is called WellDoc BlueStar DiabetesManager-Rx® System.

Both BlueStar DiabetesManager System and DiabetesManager-Rx System are implemented through an enterprise such as a health plan or large physician group in tandem with healthcare providers (HCPs) and are comprised of the following applications:

- Enterprise Director Portal
- HCP Service
- Patient Mobile Application
- Patient Web Portal

The Enterprise Director application is used for administrative purposes. The HCP Service houses the Medication Reconciliation feature (changed under K141273), which allows for the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage and frequency, by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider.

The Patient Web Portal and the Patient Mobile application have a similar feature set. Data entered into these applications is stored in the database and can be retrieved for display in either application. Both applications require the initial web- or mobile-based registration before the patient can access them. Patients are identified by healthcare providers and an access code is provided to allow access to both the web and mobile applications. On the patient applications (Mobile and Web), the basic DiabetesManager System functions as an information repository [logbook and Personal Health Record (PHR)], diabetes education resource (learning library and health tips), educational messaging/coaching, and secure communication system (Message Center). If and when a prescription is obtained, additional functions become available to the patient as DiabetesManager-Rx System. Prescription functions include additional medication information (dose and schedule), enhanced coaching [(Blood Glucose (BG) real-time coaching feedback), messaging (Message Center Content), and workflow and decision support for healthcare providers. The patient web portal and mobile application also provide an insulin dosing calculator to allow patients to use their prescribed regimen to calculate a dose of insulin for a given amount of carbohydrates and/or blood glucose value.

With this 510(k), BlueStar will have FDA clearance to connect to the One Touch Verio Flex Blood Glucose Meter (K150214) via Bluetooth. This will allow users to send data from their meter to the BlueStar app, which will provide coaching messages (motivational, behavioral, and educational) based on the real-time blood glucose values and trends. The BlueStar Server will also have the ability to transmit data to the OneTouch Reveal Server. These modifications do not change the fundamental scientific technology or the indications for use of the device.

Indications for Use

DiabetesManager® (OTC Use): The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older -who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

DiabetesManager®-Rx (Prescription Use): The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have type 2 diabetes. The DiabetesManager®-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager®-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Summary of Technological Characteristics (compared to the predicate)

Intended use, design, materials, and performance are substantially equivalent to the predicate devices referenced. The only major differences between the subject and predicate devices are the ability to connect to the OneTouch Verio Flex Blood Glucose Meter via Bluetooth and the ability to transmit data from the BlueStar Server to the OneTouch Reveal Server. This modification does not change the fundamental scientific technology of the BlueStar application, as outlined in the Indications for Use:

- Provides secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management
- Analyzes and reports blood glucose test results and supports medication adherence
- Provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends

The subject change simply provides an alternative means of blood glucose inputs but processes the inputs in the same way as the predicate device. It should be noted that the user can continue to enter blood glucose values manually (as cleared under K100066); the subject modification allows for another means of BG inputs and is not necessary to use the app and receive feedback.

Please refer to the table below for a comparison of the subject and predicate devices. Note that while both the predicate and subject device contain an insulin dose calculator with substantially equivalent functionality, the predicate device was not identified with the NDC product code at the time of clearance.

Feature	Subject Device	Predicate Device, K100066
Indications for Use	DiabetesManager (OTC Use): The WellDoc DiabetesManager ® System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older - who have type 2 diabetes. The DiabetesManager System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. The DiabetesManager System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment. DiabetesManager-Rx (Prescription Use): The WellDoc DiabetesManager -Rx System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older - who have type 2 diabetes. The DiabetesManager-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager -Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager -Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and	Identical

	trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. The DiabetesManager-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.	
OTC or Rx	Both	Both
Product Code	LNX, MRZ, NDC	LNX, MRZ
Classification	21 CFR 880.5725	Same
Class	II	II
Connection to BT meter	Yes	No
Data transmission to OneTouch Reveal Server	Yes	No
Manual Data Entry	Yes	Yes
Logbook	Yes	Yes
Coaching Messages (Motivational, Behavioral, and Educational) based on real-time blood glucose values and trends	Yes	Yes
Supported Mobile Platforms	iPhone, Android	Same
Mobile Form Factors	Candy Bar, Touch Screen	Same
Mobile Environmental Operating Systems	iOS 9.X and above Android 4.3 and above	iOS 7.X and 8.X Android 4.X
Insulin dose calculator	Yes	Yes

Non-Clinical Performance Data

Documentation according to FDA's Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and Guidance for Industry and FDA Staff: Content of Premarket Submissions for the Management of Cybersecurity in Medical Devices was provided. Verification, validation and human factors testing were performed to ensure that the device meets its requirements and intended use. Testing showed that data was transmitted successfully from the OneTouch Verio Flex BG meter and to

the One Touch Reveal Server, that the app is compatible with the mobile environmental operating systems, and that the system functions as intended.

Conclusions Drawn from Non-Clinical Tests

The non-clinical testing demonstrated that the product is substantially equivalent to the predicate and continues to meet the cleared indications for use.