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

May 21, 2024

Re: K162532
Trade/Device Name: WellDoc® BlueStar®, WellDoc® BlueStar® Rx
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 January 12, 2017. 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 Marianela Perez-Torres, OHT7: Office of In Vitro Diagnostics Devices, 301-796-1489, Marianela.Perez-Torres@fda.hhs.gov.

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Director
DHT7: Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics 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

January 12, 2017

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

Re: K162532
Trade/Device Name: WellDoc® BlueStar®, WellDoc® BlueStar® R_x
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, LNX, NDC
Dated: January 7, 2016
Received: January 9, 2017

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)*
K162532

Device Name
WellDoc® BlueStar®

Indications for Use *(Describe)*
The WellDoc BlueStar® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have type 2 diabetes. The BlueStar 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 BlueStar® System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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 BlueStar® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K162532

Device Name
WellDoc® BlueStar® Rx

Indications for Use *(Describe)*
The WellDoc BlueStar® 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 BlueStar 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 BlueStar® Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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. BlueStar® Rx includes an insulin dose 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.

The BlueStar® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K162532

General Information

Date of Summary Preparation: December 19, 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®, WellDocÈ BlueStar® Rx
Common or Usual Name:	Medical computers and software Infusion pump accessories
Product Codes:	MRZ, LNX, NDC
Classification Name:	Infusion Pump 21 CFR 880.5725 (Infusion Pump)
Regulatory Class:	II
Classification Panel:	General Hospital

Predicate Device:	K100066 (WellDoc DiabetesManager® System and Diabetes Manager®-Rx System)
Reference Device:	K162225 (WellDoc BlueStar®/ DiabetesManager® System and Diabetes Manager®-Rx System)

Device Description

WellDoc® BlueStar® is a stand-alone software system intended to be used by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have Type 2 Diabetes. The system is intended to assist Type 2 Diabetes patients to self-manage their disease, as cleared under K100066. Patients receive guidance on diabetes self-management and are encouraged to reach out to their healthcare team when needed. There are two versions of BlueStar® – BlueStar® and BlueStar® Rx – which differ in the availability of the insulin dose calculator, which is restricted to a prescription from a HCP.

BlueStar® and BlueStar® Rx are implemented through an enterprise such as a health plan or large physician group in tandem with a patient's healthcare team 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 (unchanged since cleared under K100066). The HCP Service houses the Medication Reconciliation feature, 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 (cleared under K141273).

The Patient Web Portal and the Patient Mobile application have a similar feature set (unchanged since cleared under K100066). Data (including blood glucose values, medications, carbohydrates, and activity) 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. On the patient applications (Mobile and Web), BlueStar® and BlueStar® Rx function as an (1) information repository (logbook and Personal Health Record) and (2) diabetes education resource (learning library and health tips) and provide (3) motivational, behavioral, and educational coaching based on real-time blood glucose values and trends, (4) a secure communication system (Message Center), (5) medication information (dose and schedule), and (6) workflow and decision support for healthcare providers.

In BlueStar® Rx, 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. The insulin dose calculator is restricted to prescription-use only.

Furthermore, as cleared under K162225 (reference device), BlueStar® and BlueStar® Rx have the ability 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® and BlueStar® Rx 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 of the device.

Indications for Use

OTC: The WellDoc BlueStar® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have type 2 diabetes. The BlueStar 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 BlueStar® System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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 BlueStar® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Rx: The WellDoc BlueStar® 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 BlueStar 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 BlueStar® Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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. BlueStar® Rx includes an insulin dose 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.

The BlueStar® 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 device referenced. The differences between the subject and predicate devices are: (1) the ability to connect to the OneTouch Verio Flex Blood Glucose Meter via Bluetooth (to transmit BG values taken by the meter) and the ability to transmit data from the BlueStar Server to the OneTouch Reveal Server (as cleared under K162225); (2) change in indications for use to specify the insulin dose calculator as prescription-only (in BlueStar® Rx); and (3) change in indications for use to allow the coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends to be accessed over-the-counter (in both BlueStar® and BlueStar® Rx).

The modifications herein do not change the fundamental scientific technology of the BlueStar application and do not change the subject device's substantial equivalence to the predicate device.

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	Reference Device, K162225
Indications for Use	OTC: The WellDoc BlueStar® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have type 2 diabetes. The BlueStar 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 BlueStar® System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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 BlueStar® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment. Rx: The WellDoc BlueStar® 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 BlueStar Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to	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	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

	aid in diabetes self-management. The BlueStar® Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar 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. BlueStar® Rx includes an insulin dose 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. The BlueStar® Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.	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.	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	OTC, Rx	OTC, Rx	OTC, Rx
Product Code	LNX, MRZ, NDC	LNX, MRZ	LNX, MRZ, NDC
Classification	21 CFR 880.5725	21 CFR 880.5725	21 CFR 880.5725
Class	II	II	II
Data Provided to Support Substantial Equivalence (Performance Data)	Software Verification, Software Validation, Human Factors Testing	Software Verification, Software Validation, Human Factors Testing	Software Verification, Software Validation, Human Factors Testing
Manual Data Entry	Yes	Yes	Yes
Logbook (BG values, Carbs, Activity)	Yes	Yes	Yes
Real-time Feedback on BG values (coaching messages)	Yes	Yes	Yes

Pattern Detection, Graphs, Charts	Yes	Yes	Yes
Ability to Log Medications	Yes	Yes	Yes
Medication Management (reminders, integration with drug database)	Yes	Yes	Yes
Ability to Share Data and Reports	Yes	Yes	Yes
Supported Mobile Platforms	iPhone, Android	iPhone, Android	iPhone, Android
Insulin Dose Calculator	Yes (**Rx-only**)	Yes	Yes (**Rx-only**)
Connection to BT meter	Yes	No	Yes
Data transmission to OneTouch Reveal Server	Yes	No	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 showed that the system can be used by a layperson without HCP oversight, meets its requirements and functions as intended. Note that the insulin dose calculator can only be used under the oversight of a HCP.

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 intended use.