April 7, 2020

WellDoc, Inc
Sabyasachi Roy
Vice President Regulatory and Quality Systems
10221 Wincopin Circle, Suite 150
Columbia, MA 21044

Re: K193654
Trade/Device Name: BlueStar® Rx
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ, NDC, LNX
Dated: March 4, 2020
Received: March 4, 2020

Dear Sabyasachi Roy:

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 and Part 809); 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193654

Device Name
BlueStar® Rx

Indications for Use *(Describe)*

BlueStar® Rx is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. The BlueStar® Rx 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 analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar® Rx 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.

• For bolus insulin users with type 1 and type 2 diabetes, BlueStar® Rx includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or blood glucose value.

• For basal insulin users with type 2 diabetes, BlueStar® Rx includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider knowledgeable in the care and management of diabetes. The healthcare provider must activate the Insulin Adjustment Program and configure it for patient-specific parameters.

The BlueStar® Rx 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

Date Prepared:	December 30, 2019
Name of Manufacturer:	WellDoc, Inc.
Address:	10221 Wincopin Circle, Suite 150 Columbia, MD 21044
Contact Person:	Sabyasachi Roy, MSEE, Ph.D. VP, Regulatory and Quality Systems
Phone:	(443) 692-3100
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Trade or Proprietary Name:	BlueStar® Rx
Common or Usual Name:	Medical computers and software Infusion pump accessories
Product Codes:	Classification: MRZ, Secondary: NDC, LNX
Regulation:	21 CFR 880.5725 – Accessories, Pump, Infusion 21 CFR 868.1890 – Calculator, Drug dose
Regulatory Class:	II
Classification Panel:	General Hospital, Clinical Chemistry
Primary Predicate Device:	K190013 (WellDoc® BlueStar® and WellDoc® BlueStar® Rx System)
Secondary Predicate Device:	K171450 (Glooko Mobile Insulin Dosing System (MIDS))

Device Description

BlueStar Rx is a modified version of the primary predicate (WellDoc BlueStar Rx cleared under K190013). BlueStar Rx maintains all of the features of the primary predicate and adds the titration of long-acting basal insulin doses for qualified type 2 diabetes patients who are not using bolus insulin. This long-acting basal insulin titration feature is included as part of the Insulin Adjustment Program (IAP) in BlueStar Rx. WellDoc BlueStar® as cleared under K190013, is a stand-alone software system intended to be used by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. The system is intended to assist type 1 and type 2

diabetes patients to self-manage their disease. Patients receive guidance on diabetes self-management and are encouraged to reach out to their healthcare team when needed. There are two versions of the primary predicate WellDoc BlueStar® (cleared under K190013) – BlueStar® (OTC version) and BlueStar® Rx (prescription only) applications. In this submission, Welldoc does not propose to change the OTC version of BlueStar application. Like the bolus insulin dose calculator already included in the primary predicate (BlueStar Rx), the new long-acting basal insulin titration feature is also limited to the prescription use (Rx) version. The bolus insulin calculator feature will be disabled in patients using long-acting basal insulin titration feature in the BlueStar Rx. Health care providers (HCPs) will be required to initiate and manage the basal insulin titration for their qualified type 2 diabetes patients using the following two interfaces:

- Web based HCP interface for use by the providers to prescribe long-acting basal insulin doses for the qualified type 2 diabetes patients.

- Web and mobile patient interface for use by patients to follow provider's basal insulin titration plan.

The IAP feature in BlueStar Rx provides directions to the patients based on prescription by their HCP for titrating long-acting insulin doses only.

BlueStar® Rx will also maintain the following features of the primary predicate (WellDoc BlueStar Rx cleared under K190013): (1) ability to connect to the One Touch Verio Flex Blood Glucose Meter via Bluetooth which allows users to send data from their BG meter to the BlueStar® Rx app, which will provide coaching messages (motivational, behavioral, and educational) based on the real-time blood glucose values and trends. (2) The BlueStar Server will also have the ability to transmit data to the OneTouch Reveal Server. With this application, 3-hour delayed continuous glucose monitoring device data can be accessed via API and uploaded for data visualization purposes only.

Indications for Use

BlueStar® Rx is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. The BlueStar® Rx 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 analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar® Rx 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.

- For bolus insulin users with type 1 and type 2 diabetes, BlueStar® Rx includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or blood glucose value.

- For basal insulin users with type 2 diabetes, BlueStar Rx includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider. The healthcare provider must activate the Insulin Adjustment Program and configure it for patient-specific parameters.

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

Comparison to Predicates

Feature	BlueStar Rx (Subject Device)	WellDoc BlueStar Rx System (Primary Predicate Device)	Glooko Mobile Insulin Dosing System (MIDS) (Secondary Predicate)
Product Code	MRZ, NDC, LNX	MRZ, NDC, LNX	NDC
Class	II	II	II
Regulation	21 CFR 880.5725: Accessories, Pump, Infusion 21 CFR 868.1890: Calculator, Drug dose	21 CFR 880.5725: Accessories, Pump, Infusion 21 CFR 868.1890: Calculator, Drug dose	21 CFR 868.1890: Calculator, Drug dose
510(k) Number	K193654	K190013	K171450
Indications for Use	Rx: BlueStar® Rx is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. The BlueStar® Rx 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 analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar® Rx 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	Rx: The WellDoc BlueStar® Rx System is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or 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	The Glooko Mobile Insulin Dosing System (MIDS) is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a physician or healthcare provider knowledgeable in the care and management of diabetes. The physician or healthcare provider must activate the MIDS dose calculator and configure the patient-specific parameters. The system is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Feature	BlueStar Rx (Subject Device)	BlueStar Rx System (Primary Predicate Device)	Glooko Mobile Insulin Dosing System (MIDS) (Secondary Predicate)
	in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. • For bolus insulin users with type 1 and type 2 diabetes, BlueStar® Rx includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or blood glucose value. • For basal insulin users with type 2 diabetes, BlueStar Rx includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider. The healthcare provider must activate the Insulin Adjustment Program and configure it for patient-specific parameters. The BlueStar® Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.	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.	
Environment of Use	Home or Clinic	Home or Clinic	Home or Clinic

Feature	BlueStar Rx (Subject Device)	WellDoc BlueStar Rx System (Primary Predicate Device)	Glooko Mobile Insulin Dosing System (MIDS) (Secondary Predicate)
Type of Insulin Adjustment	Bolus Insulin Calculation and Basal (long-acting) Insulin Titration	Bolus Insulin Calculation	Basal (long-acting) Insulin Titration
Titration Plan	HCP determined	N/A	HCP determined
Basal Titration Safety Features	- Suspends titration on hypoglycemia - Suspends titration on unsafe dose - Maximum dose set by HCP (system limits to 100-units) - Fasting BG reminder - Insulin injection reminder - Report to HCP	N/A as Basal Titration not included	- Suspends titration on hypoglycemia - Suspends titration on unsafe dose - Maximum dose set by HCP - Fasting BG reminder - Insulin injection reminder - Report to HCP
Safety Notifications	Yes (Hyper notification with instructions; Hypo notification with instructions; Unsafe dose; Maximum dose)	N/A for Basal Titration	Yes (Hyper notification with instructions; Hypo notification with instructions; Unsafe dose; Maximum dose)
Basal Titration Status	Active Suspended Ended	N/A for Basal Titration	Active Inactive Alert Adherence Ended
Logbook	Yes	Yes	Yes
Technological Characteristics			
Interface	Patient interface – web and mobile application HCP interface – web Includes support for iOS, Android and web browsers such as Internet Explorer, Chrome, Firefox, Safari.	Patient interface – web and mobile application HCP interface – web. Includes support for iOS, Android and web browsers such as Internet Explorer, Chrome, Firefox, Safari and others.	Patient interface – web and mobile application HCP interface – web Includes support for iOS, Android and web browsers such as Internet Explorer, Chrome, Firefox, Safari.
Reports & Statistics	Yes	Yes	Yes
Secure Database	Yes	Yes	Yes
Data Transfer Mode	Internet	Internet	Internet

Discussions of differences in Indications for Use statement:

As compared to the previously cleared version of the BlueStar® Rx, the subject device of this

application proposes to make the following changes:

- Requires HCPs to initiate and manage long-acting basal insulin titration for their patients with type 2 diabetes

The indications for use of the subject device clearly reflects this new basal insulin titration capability in the statement included:

> "For basal insulin users with type 2 diabetes, BlueStar Rx includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider. The healthcare provider must activate the Insulin Adjustment Program and configure it for patient-specific parameters."

This statement is equivalent to the secondary predicate's (Glooko MIDS) indications for use as noted in the table above.

Discussions of differences in technological characteristics:

The subject device includes all of the features of the WellDoc BlueStar® Rx system cleared under K190013 and is technologically similar to the secondary predicate – Glooko MIDS. The subject device maintains all of the technological capabilities of the primary predicate (BlueStar® and BlueStar® Rx) including:

- the ability to connect to the One Touch Verio Flex Blood Glucose Meter 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 also has the ability to transmit data to the OneTouch Reveal Server. With this application, 3-hour delayed continuous glucose monitoring device data can be accessed via API and uploaded for data visualization purposes only.

The inclusion of the basal insulin titration under the Insulin Adjustment (IAP) feature in the subject device does not interfere with the existing functionality cleared in the WellDoc BlueStar® and WellDoc BlueStar® Rx app under K190013.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence ofthe subject device:

Software	• Software verification and validation per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) for a **Major Level of Concern** • FDA Guidance "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices"

Cybersecurity	• Cybersecurity was evaluated per the FDA Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff, (October 2, 2014). Specifically, addressing the following areas: Identify and Protect, Detect, Response and Recover
Human Factors	• Human factors testing was conducted with the intended user populations of patients and healthcare providers. The human factors, design, and labeling information provided in the submission confirm that the user interface has been adequately validated for use per the labeling.

Clinical Tests

Not Applicable.

Conclusions

The subject device in this premarket notification – BlueStar® Rx with the Insulin Adjustment Program (IAP) feature has similar indications for use and technological characteristics as those of the predicate devices (WellDoc BlueStar® Rx cleared under K190013 and Glooko MIDS cleared under K171450).

Performance testing demonstrated that the BlueStar® Rx performed as intended. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The BlueStar Rx is substantially equivalent to the predicates cited.