



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY**

I Background Information:

A 510(k) Number

K193654

B Applicant

WellDoc, Inc

C Proprietary and Established Names

BlueStar® Rx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MRZ	Class II	21 CFR 880.5725 - Infusion Pump	General Hospital
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	Clinical Chemistry
LNx	Unclassified		

II Submission/Device Overview:

A Purpose for Submission:

Addition of a new functionality to an existing device.

B Type of Test:

Insulin dose (basal and bolus) calculation and titration.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

BlueStar® Rx is not indicated for people with gestational diabetes or who use an insulin pump. Basal Insulin Titration is not for people who are treated with bolus insulin.

The BlueStar® Insulin Adjustment Program is designed to work with glucose results reported in mg/dL and cannot safely be used with mmol/L values. To avoid harm please ensure that any glucose meter used with the BlueStar® Insulin Adjustment Program system is set for blood glucose values in mg/dL.

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A 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 type 2 diabetes patients who are not using bolus insulin. WellDoc BlueStar® Rx, a prescription only device 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. An over the counter (OTC) version of the device, WellDoc BlueStar®, was also cleared in K190013; this submission includes no changes to the OTC device. Like the bolus insulin dose calculator already included in the predicate (WellDoc BlueStar® Rx), the new long-acting basal insulin titration feature is also limited to the prescription use (Rx) only device version.

The new basal titration feature is only for patients who are taking basal insulin without any bolus insulin. The basal titration feature is for use with the following long-acting insulins: Lantus and Basaglar (U100 glargine), Toujeo (U300 glargine), Levemir (detemir), and Tresiba (degludec). The basal titration feature can also be used to titrate the following long-acting insulin / GLP-1 agonist products: Soliqua (glargine/lixisenatide), and Xultrophy (degludec/liraglutide).

The bolus insulin calculator feature will therefore be disabled for patients using the 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 feature for 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 type 2 diabetes patients.
- Web and mobile patient interface for use by patients to follow provider's basal insulin titration plan.

The 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 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 (CGM) device data can be accessed via API and uploaded for data visualization purposes only. CGM data is not used by the BlueStar® Rx device for insulin dose calculation or titration.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

BlueStar® Rx

2. Specimen Identification:

Not Applicable.

3. Specimen Sampling and Handling:

Not Applicable.

4. Calibration:

Not Applicable.

5. Quality Control:

Not Applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):

WellDoc BlueStar® Rx

B Predicate 510(k) Number(s):

K190013

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K193654</u>	<u>K190013</u>
Device Trade Name	BlueStar® Rx	WellDoc BlueStar® Rx
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Determination of insulin dose based on user entered data
Environment of use	Same	Home use
User Interface	Same	Mobile App and HCP Portal
User Group	Same	Persons with type 1 or type 2 diabetes
General Device Characteristic Differences		
Type of insulin dose calculation	Bolus dose calculation or basal insulin titration	Bolus dose calculation
Type of insulin	Short acting or long acting insulins (Lantus, Basaglar, Toujeo, Levemir, Tresiba, Soliqua, or Xultrophy)	Short acting insulin

VI Standards/Guidance Documents Referenced:

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

FDA Guidance for Off-the-Shelf Software Use in Medical Devices (September 27, 2019)

FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Not Applicable.

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Not Applicable.

4. Accuracy (Instrument):

Not Applicable.

5. Carry-Over:

Not Applicable.

B Other Supportive Instrument Performance Characteristics Data:

Usability:

The sponsor provided protocols and results from human factors studies to demonstrate that users can perform all critical tasks associated with the new device features. Subjects were representative of the device's intended use population, including patients over 18 years of age and healthcare providers. The results of these studies were adequate to demonstrate safe use of the device and support substantial equivalence to the predicate.

Software:

The firm provided software documentation consistent with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005), and consistent with software with a major level of concern. Software documentation was acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.