510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K203434

B Applicant

WellDoc, Inc.

C Proprietary and Established Names

BlueStar® Rx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	Clinical Chemistry

E Purpose for Submission:

Modification of a cleared device to add the bolus titration feature and compatibility with pre-mixed insulin.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BlueStar@ Rx is indicated for use by healthcare providers (HCPs) and their patients - aged 18 years and older - who have type I or type 2 diabetes. 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. BlueStar Rx analyzes, and reports blood glucose test results and supports medication adherence. In addition, 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 or 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.
- For bolus insulin users with type 2 diabetes, BlueStar Rx's IAP calculates appropriate dose adjustments of bolus insulin based on configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets despite optimization of their basal insulin dose or their current bolus insulin regimen.
- For premixed insulin users with type 2 diabetes, BlueStar Rx's IAP calculates appropriate dose adjustments of premixed insulin based on the configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets and who do not take other types of insulin.

The algorithms for the IAP are not designed for the titration of NPH, regular human insulin, or human premixed insulins.

The healthcare provider must activate the IAP and configure it with patient-specific parameters. BlueStar Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment." It is for Rx use.

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.

The BlueStar Rx 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 BlueStar is set for blood glucose values in mg/dL.

III Device Description

Subject device (BlueStar Rx) is a modified version of the primary predicate (BlueStar Rx cleared under K193654). BlueStar Rx maintains the basic features / functionality of the primary predicate and adds the titration of fast-acting bolus insulin doses and premixed insulins for qualified type 2 diabetes patients. Qualified patients are those with type 2 diabetes whose blood glucose is not adequately managed on current insulin therapies (e.g., using basal insulin) and/or non-insulin therapies.

This bolus insulin and premixed titration feature is included as part of the expanded Insulin Adjustment Program (IAP) in BlueStar Rx. The primary predicate (BlueStar Rx, K193654) 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, are encouraged to reach out to their healthcare team when needed and have access to a bolus insulin calculator1. The insulin adjustment program (IAP) of the primary predicate (BlueStar Rx, K193654) already includes the ability to titrate long-acting basal insulin for patients with type 2 diabetes. In this submission, fast-acting bolus insulin and premixed insulin titration features are added to the subject device's (BlueStar Rx) IAP for patients with type 2 diabetes.

Health care providers (HCPs) will be required to initiate and manage the titration of basal, bolus and premixed 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 insulin doses for the qualified type 2 diabetes patients.
- Web and mobile patient interface for use by patients to follow provider's insulin titration plan.

The IAP feature in subject device (BlueStar Rx) provides directions to the patients based on prescription by their HCP for titrating basal, bolus and premixed insulin doses.

IV Substantial Equivalence Information:

A Predicate Device Name(s):
BlueStar® Rx

B Predicate 510(k) Number(s):
K193654

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203434	K193654
Device Trade Name	**BlueStar Rx (Subject Device)**	**BlueStar Rx (Primary Predicate Device)**
General Device Characteristic Similarities		
Intended Use/Indications For Use	Determination of insulin dose based on user entered data	Same
Environment of Use	Home Use	Same
User Interface	Mobile App and HCP Portal	Same
User Group	Persons with type 1 or type 2 diabetes	Same

Basal Insulin Titrated	Basal (long-acting) Insulins: • glargine - U100 (Lantus, Basaglar) • glargine - U300 (Toujeo) • detemir (Levemir) • degludec (Tresiba) Basal Insulin + GLP-1 agonist • glargine/Lixisenatide (Soliqua) • degludec/liraglutide (Xultophy)	Same
General Device Characteristic Differences		
Bolus insulin titrated	• Admelog U-100 • Apidra U-100 • Fiasp U-100 • Humalog U-100 • Humalog U-200 • Novolog U-100	None
Premixed insulin titrated	• Humalog Mix 75-25(U-100) Insulin • Novolog Mix 70-30 FlexPen U-100 • Novolog Mix 70-30 U-100 Insulin • Humalog Mix 75-25 KwikPen	None

V 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)

VI Performance Characteristics:

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.

VII Proposed Labeling:

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

VIII Conclusion:

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