September 8, 2021

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

Re: K203434
Trade/Device Name: BlueStar® Rx
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: November 20, 2020
Received: November 23, 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 -S

Marianela Perez-Torres, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203434

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. 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 to aid in diabetes self-management.

• 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.

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.

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"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

Date Prepared:	September 03, 2021
Name of Manufacturer:	WellDoc, Inc.
Address:	10221 Wincopin Circle, Suite 150 Columbia, MD 21044
Contact Person:	Sabyasachi Roy, MSEE, Ph.D. Vice President, Regulatory Affairs
Phone:	(443) 692-3100
Fax:	(443) 692-3099
Trade or Proprietary Name:	BlueStar® Rx
Common or Usual Name:	Calculator, Drug Dose
Product Codes:	NDC
Regulation:	21 CFR 868.1890 – Calculator, Drug dose
Regulatory Class:	II
Classification Panel:	Clinical Chemistry
Predicate Device:	BlueStar® Rx (K193654)

Device Description

Subject device (BlueStar® Rx) is a modified version of the predicate (BlueStar® Rx cleared under K193654). BlueStar® Rx maintains the basic features / functionality of the 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 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. Like the predicate, the subject device (BlueStar® Rx) is intended to provide secure capture, storage, and transmission of blood glucose data as well as other information to aid in diabetes self-management. 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 calculator[1]. The insulin adjustment program (IAP) of the 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.

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. 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 to aid in diabetes self-management.

- For bolus insulin users with type 1 or type 2 diabetes, BlueStar® Rx includes an insulin

[1] Bolus insulin calculator was previously cleared for Welldoc BlueStar® Rx under K190013.

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.

Comparison to Predicates

Feature	BlueStar® Rx (Subject Device)	BlueStar® Rx (Predicate Device)
Product Code	NDC	MRZ, NDC, LNX
Class	II	II
Regulation	21 CFR 868.1890: Calculator, Drug dose	21 CFR 880.5725: Accessories, Pump, Infusion 21 CFR 868.1890: Calculator, Drug dose
510(k) Number	K203434	K193654
Target Population for insulin titration	Qualified Type 2 diabetes patients ≥18 years requiring intensification of insulin; and their provider	Qualified Type 2 diabetes patients ≥18 years requiring intensification of insulin; and their provider
Environment of Use	Home under direction of HCP and Clinic	Home under direction of HCP and Clinic
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. 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	The WellDoc 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

Feature	BlueStar® Rx (Subject Device)	BlueStar® Rx (Predicate Device)
	diabetes-related healthcare information and provides educational information to aid in diabetes self-management. • 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.	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.
Software Based	Yes	Yes
Platform	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 Edge.	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 Edge.
Basal Insulin Titrated	Basal (long-acting) Insulins: - glargine - U100 (Lantus, Basaglar) - glargine - U300 (Toujeo) - detemir (Levemir) - degludec (Tresiba)	Basal (long-acting) Insulins: - glargine - U100 (Lantus, Basaglar) - glargine - U300 (Toujeo) - detemir (Levemir) - degludec (Tresiba)

Feature	BlueStar® Rx (Subject Device)	BlueStar® Rx (Predicate Device)
	Basal Insulin + GLP-1 agonist - glargine/Lixisenatide (Soliqua) - degludec/liraglutide (Xultophy)	Basal Insulin + GLP-1 agonist - glargine/Lixisenatide (Soliqua) - degludec/liraglutide (Xultophy)
Bolus insulin titrated	• Admelog U-100 • Apidra U-100 • Fiasp U-100 • Humalog U-100 • Humalog U-200 • Novolog U-100 *See Note-3*	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 *See Note-3*	None
HCP Involvement	HCP inputs are entered and confirmed using the HCP web portal. HCP can monitor and adjust treatment plan.	HCP inputs are entered and confirmed using the HCP web portal. HCP can monitor and adjust treatment plan.
Patient Involvement	Patient can record actual dose taken	Patient can record actual dose taken.
Primary HCP Inputs (titration)	Insulin type Titration parameters & rules - Initial insulin dose - Maximum dose - Optional (correction factor and IOB) - Algorithm Titration parameters (e.g., insulin increment, interval, BG target) are set based on evidence based titration algorithms.	Insulin type Titration parameters & rules - Initial insulin dose - Interval of titration - Increment of insulin - Maximum dose - Fasting BG target range - Below / above BG target & corresponding insulin adjustment Titration parameters may be selected from evidence-based titration algorithms or HCP's custom prescription for basal insulin.
Patient inputs	• Glucose: Fasting, Current (e.g., Pre-Meal, Bedtime) • Dose: record insulin dose to reflect actual dose taken • Event Type for current glucose • reading (e.g., Breakfast) • Carbs for Basal-bolus with Carb counting (in app support for carb counting)	• Glucose: Fasting, Current (e.g., Pre-Meal, Bedtime) • Dose: record insulin dose to reflect actual dose taken • Event Type for current glucose • reading (e.g., Breakfast) • Carbs for Basal-bolus with Carb counting (in app support for carb counting) No support for bolus and premixed insulin titration / IAP.
Primary Output for Diabetes	To Patient- Provides warnings and coaching / RTFB when blood glucose values exceed hypoglycemic or hyperglycemic limits;	Basal algorithms see K193654 510(k) Summary

Feature	BlueStar® Rx (Subject Device)	BlueStar® Rx (Predicate Device)
Management	provides recommended adjustments to the prescribed insulin dose; tracks blood glucose and insulin data; send SMART visit report to HCP. To HCP – alerts when blood glucose values exceed hypoglycemic or hyperglycemic limits or patient deviates from prescribed regimen; and view titration progress and summary report. *See Note-3*	No bolus or premixed titration algorithms.
Limits for Safety	The system provides hypoglycemia coaching instructions; bolus insulin algorithm is constrained to a 4 unit dosage increase over a 3 day period (Q3D); maximum insulin dose is 30 units per dose for both bolus (Insulin-to-Carbohydrate Ratio) and 70 units premix insulin (see Note-1). *See Note-3*	Basal algorithms see K193654 510(k) Summary No bolus or premixed algorithms.
Warnings	Hypoglycemia and Hyperglycemia coaching instructions; patient deviates from prescribed regimen; Alerts sent to HCPs. *See Note-3*	Basal algorithms see K193654 510(k) Summary No bolus or premixed algorithms.
Logbook	Yes	Yes
Reports & Statistics	Yes	Yes
Secure Database	Yes	Yes
Data Transfer Mode	Internet	Internet
Algorithm Used	Bolus Insulins • Humalog, Apidra, Novolog - AUTONOMY ICR • Apidra – Adjust to Target Premixed Insulin • INITIATE • Real-World Approach (Hirsch et al. 2005) *See Note-2 and Note-3*	Basal algorithms see K193654 510(k) Summary No bolus or premixed titration algorithms.
Glucose Target	Q1D or Q3D - BG Target Range (not-editable) 85 - 114 mg/dL Q7D-ICR - BG Target Range (not-editable) 80 - 130 mg/dL	Basal algorithms see K193654 510(k) Summary No bolus or premixed titration algorithms.
Magnitude of insulin adjustment as a function of target	The incremental dose adjustment does not change as a function of target; the dose adjustment is based on the algorithm used in clinical studies.	Basal algorithms see K193654 510(k) Summary No bolus or premixed titration algorithms.
Limits on	No dosing recommendation for Hypoglycemia;	Basal algorithms see K193654 510(k)

Feature	BlueStar® Rx (Subject Device)	BlueStar® Rx (Predicate Device)
insulin adjustment	Bolus insulin algorithm is constrained to a 4unit dosage increase per 3-day period (Q3D); maximum insulin dose is 30 units per dose for bolus (Insulin-to-Carbohydrate Ratio) and 70 units for premix insulin.	Summary No bolus or premixed titration algorithms.
Frequency of insulin adjustment (increase)	No more than once daily.	Basal algorithms see K193654 510(k) Summary No bolus or premixed titration algorithms.
Frequency of insulin adjustment (decrease)	Daily decrease allowed.	Basal algorithms see K193654 510(k) Summary No bolus or premixed titration algorithms.
Note-1: Premixed insulin is a combination of long-acting (basal) and fast-acting (bolus) insulin in one injection. In a 70/30 premix, only 30% of the insulin is bolus. Therefore, the total max dose for premix can be higher than the max dose for bolus. *Note-2: Edelman et al. 2014 (AUTONOMY study / algorithm); Raskin et al 2005 (INITIATE study / algorithm); Bergenstal et al. 2008 (Adjust to Target in Type 2 Diabetes); Hirsch et al. 2005 (Real-World Approach).* *Note-3: Similar to other devices such as Go Dose System (K160949) and d-Nav System (K181916).*		

Discussions of similarities and differences in Indications for Use statement:

The subject device (BlueStar® Rx), and predicate (BlueStar® Rx, K193654) share the following similarities:

- Devices use blood glucose value to calculate a recommended insulin dose in order to aid in optimal insulin management.
- Devices are used by similar target population. With regards to insulin titration feature, both devices are intended for patients with type 2 diabetes.
- Devices are prescription use and used in home and clinical settings.
- Device software operate on the basic setup where an HCP configures, initiates and then oversees the insulin titration process.
- Information for diabetes management is provided in both devices.
- None of the devices are intended to be a substitute for professional clinical advice.

Compared to the predicate (BlueStar® Rx, K193654), the subject device proposes to make the following changes:

- Expand the Insulin Adjustment Program (IAP) to include fast-acting bolus insulin and premixed insulin titration for qualified type 2 diabetes patients

The indications for use of the subject device (BlueStar® Rx) clearly reflects this expansion of the IAP capability in the two additional statement included:

> "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."

These statements are equivalent to the indications of the predicate (BlueStar® Rx, K193654) and other devices such as (Go Dose System, K160949; d-Nav System, K181916).

The difference in indications for use do not raise any new questions of safety or effectiveness. The subject device and predicate have similar intended population and intended use.

Discussions of similarities and differences in technological characteristics:

The core technological characteristics between the subject device (BlueStar® Rx) and predicate (BlueStar® Rx) cleared under K193654 remain the same. The subject device (BlueStar® Rx) is built upon the predicate's software application platform. The subject device (BlueStar® Rx) incorporates the bolus and premixed insulin titrations features to the existing capabilities of the predicate without requiring any software architecture or fundamental design change. The bolus and premixed insulin titration features utilized the basic building blocks of adjusting patient's insulin under the supervision of an HCP as cleared under K193654. The bolus insulin titration features in the subject device (BlueStar® Rx) are similar to other devices such as *Go Dose System* cleared under K160949. The premixed insulin titration features in the subject device (BlueStar® Rx) are similar to other devices such as *d-Nav System* cleared under K181916. A thorough comparison of the subject device with its predicate is outlined in the table above.

The similarities between the subject device and predicate are outline as follows:

- All are insulin dose calculator software systems
- Include separate software components for use by HCP and patient
- Enable HCP to initiate and adjust insulin dosage based on individual patient's treatment plan
- Support a variety of insulin drugs, including basal, premixed and bolus insulins.
- Subject device (BlueStar® Rx) uses the identical algorithm (AUTONOMY study[2]) for bolus insulin titration as that used in device such as Go Dose System (K160949). The eligible insulins for bolus titration in the subject device are those that are fast-acting insulin analogs which is the type of insulin used in devices such as Go Dose System.
- Provide a history of responses (e.g., glucose reading) and insulin doses to both HCP and patients
- Incorporate safety features (e.g., limit max change in next dose) and warnings (e.g., hyperglycemia, hypoglycemia).

The implementation of the bolus and premixed insulin titration in the subject device (BlueStar® Rx) did not require significant changes to existing design of the predicate (BlueStar® Rx, K193654) application except:

[2] Edelman SV, Liu R, Johnson J, Glass LC. AUTONOMY: the first randomized trial comparing two patient-driven approaches to initiate and titrate prandial insulin lispro in type 2 diabetes. Diabetes Care. 2014 Aug;37(8): 2132-40. doi: 10.2337/dc13-2664. Epub 2014 Apr 17. PMID: 24742662.

- There are now RTFB / coaching messages specific to bolus titration or premixed titration; standard RTFB / coaching is turned off for users in the IAP.
- Weekly insights, trends, weekly challenge, rewards, and CGM connection are disabled (off) for users in the IAP.
- Users cannot change their diabetes type.
- Users undergoing titration cannot add other insulin (basal, bolus, or premixed) to their med list and cannot edit the insulins prescribed in their titration program.
- Users cannot undergo basal titration while in bolus or premixed titration.
- The design and function of the insulin calculator is unchanged other than a banner alerting user to an updated dosing regimen while in titration.
- The UI of the home screen and some sub-menus were updated but is not expected to significantly impact device function including usability.

The inclusion of the bolus and premixed insulin titration under the Insulin Adjustment Program (IAP) in the subject device did not interfere with the existing functionality cleared in the BlueStar® Rx app under K193654.

In terms of technological characteristics, the subject device (BlueStar® Rx) and the predicate device differ in certain minor details. However, those difference do NOT raise new questions of safety or effectiveness.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the 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 device (BlueStar® Rx, K193654).

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 predicate cited.