July 28, 2023

Welldoc, Inc.
David Boser
Director, Regulatory Affairs
10221 Wincopin Circle, Ste #150
Columbia, Maryland 21044

Re: K230813
Trade/Device Name: BlueStar® and BlueStar® Rx
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: March 23, 2023
Received: March 24, 2023

Dear David Boser:

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,

Joshua Balsam -S

Joshua Balsam, PhD
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K230813

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 is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar Rx automatically receives insulin dose related data when connected to compatible Tempo Smart Button™ device via wireless Bluetooth® technology and has the ability to detect and mark which doses are prime and which are injected insulin. BlueStar Rx analyzes and reports glucose test results and supports medication adherence. In addition, BlueStar Rx provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. 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 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 IAP and configure it for 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)

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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)*
K230813

Device Name
BlueStar®

Indications for Use *(Describe)*

BlueStar® 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 is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar automatically receives insulin dose related data when connected to compatible Tempo Smart Button™ device via wireless Bluetooth® technology and has the ability to detect and mark which doses are prime and which are injected insulin. BlueStar analyzes and reports glucose test results and supports medication adherence. In addition, BlueStar provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

BlueStar 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.

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510(k) Summary: K230813

Date Prepared:	March 23, 2023
Name of Manufacturer:	WellDoc, Inc.
Address:	10221 Wincopin Circle, Suite 150 Columbia, MD 21044
Contact Person:	David Boser Director, Regulatory Affairs
Phone:	(248) 249-5243
Fax:	(443) 692-3099
Trade or Proprietary Name:	BlueStar®, BlueStar® Rx
Common or Usual Name:	Calculator, Drug Dose
Product Codes:	Classification: NDC
Regulation:	21 CFR 868.1890 – Calculator, Drug Dose
Regulatory Class:	II
Classification Panel:	Clinical Chemistry
Predicate Device:	BlueStar® Rx (K193654)

Device Description

BlueStar® (subject device) combines the existing *diabetes self-management* features of the predicate (BlueStar® and BlueStar® Rx, K193654) with the *automatic tracking of insulin delivery* functionality of the reference InPen System (K160629). BlueStar maintains all of the features of the predicate and adds the capability to connect with compatible devices connected with insulin pens via Bluetooth wireless technology. In this submission, the predicate device is being modified such that it can receive insulin dose-related data when connected to a Tempo Smart Button™ (TSB). The TSB when attached to a disposable Tempo Pen (insulin pen), can transfer dose-related data (corresponding to the brand of insulin, dose amount, date, and time) via Bluetooth® Low Energy (Bluetooth) wireless technology.

BlueStar is a Software as a Medical Device (SaMD) intended to be used by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. BlueStar is intended to assist patients in managing their diabetes with guidance from their providers. BlueStar has two versions – BlueStar (Over the Counter, OTC) and BlueStar Rx (prescription use version).

BlueStar is comprised of the following software applications (app):

- iOS and Android based mobile apps for patients
- web-based app (web-portal) for HCPs

BlueStar requires initial registration before the patient can access the software applications.

BlueStar is compatible with devices including Blood Glucose Meters (BGM), Blood Pressure Monitors, Continuous Glucose Monitors (CGM)[1], *Tempo Smart Button*™ [2], Weight Scales, Activity Trackers. Data, including blood glucose values, blood pressure, medications, carbohydrates, physical activity, weight, and sleep are entered, stored and processed in the patient software applications. Data can be entered manually or automatically via Bluetooth for compatible devices. Additionally, the mobile application for patients is capable of automatically receiving, storing, processing, and displaying insulin data from the *Tempo Smart Button* via Bluetooth.

The BlueStar apps for patients function as an information repository (logbook and Personal Health Record) and diabetes education resource (curriculum, articles, videos). Patients also receive in-the-moment coaching (Real Time Feedback messages), Pattern Reports and SMART Visit Reports that can be shared with their providers. Coaching messages are motivational, behavioral, and educational in nature and are based on data (and trends) including real-time blood glucose, blood pressure, and weight. Patients receive guidance on diabetes self-management and are encouraged to reach out to their healthcare team when needed. Patients

1 BlueStar receives 3-hour delayed CGM data via manufacturer's API.

2 Tempo Smart Button (module), manufactured by Eli Lilly and Company, is a reusable data transmitter that detects and stores insulin dose-related data when attached to a disposable Tempo Pen, and then transfers this information to a compatible mobile application via Bluetooth® Low Energy (Bluetooth) wireless technology. The dose-related data corresponds to the brand of insulin, dose amount, date, and time. In this submission, the predicate (BlueStar, and BlueStar Rx, K193654) was modified to be compatible with the Tempo Smart Button manufactured by Eli Lilly and Company. Refer to K212217 for premarket notification for Tempo Smart Button.

also receive insights based on data entered and trends detected by the app. BlueStar patient apps include a secure communication system (Message Center) as well as a medication information repository (dose and schedule). Qualified type 1 and type 2 diabetes patients have access to a bolus insulin calculator (cleared under K190013). Qualified type 2 diabetes patients have access to the Insulin Adjustment Program (IAP) to titrate long-acting basal insulin (cleared under K193654). Patients use their mobile software applications to follow their HCP's bolus insulin prescription or basal insulin titration plan. The bolus insulin calculator and basal insulin titration features are only available in BlueStar Rx for use under the direction of their HCP.

The provider can review patient information, workflows and decision support information using the web-based software application for HCP. The HCP can initiate and manage basal insulin titration (IAP) and the bolus insulin calculator prescription / parameters through the web-based software application for HCP.

The SMART Visit Report includes data summary, analysis, and decision support for treatment as well as psychosocial issues identified by patient survey responses within the app. The SMART Visit Report can be sent by the patient to his/her HCP from the mobile app. The HCP can also generate SMART Visit Reports from their web portal.

Indications for Use

BlueStar® (OTC):

BlueStar® 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 is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar automatically receives insulin dose related data when connected to compatible Tempo Smart Button™ device via wireless Bluetooth® technology and has the ability to detect and mark which doses are prime and which are injected insulin. BlueStar analyzes and reports glucose test results and supports medication adherence. In addition, BlueStar provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

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

BlueStar® 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. BlueStar Rx is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar Rx automatically receives insulin dose related data when connected to compatible Tempo Smart Button™ device via wireless Bluetooth® technology and has the ability to detect and mark which doses are prime and which are injected insulin. BlueStar Rx analyzes and reports glucose test results and supports medication adherence. In addition, BlueStar Rx provides coaching messages (motivational, behavioral, and educational) based on

real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. 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 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 IAP and configure it for 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

Note-1: BlueStar Rx includes features of BlueStar (OTC version). The bolus insulin calculator and basal insulin titration under (Insulin Adjustment Program – IAP) are only available in BlueStar Rx.

Feature	**BlueStar (Subject Device)**	**BlueStar Rx (Predicate – K193654)**
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	K230813	K193654
Intended patient population	For patients aged 18 years and older who have type 1 or type 2 diabetes. Basal insulin titration is for type 2 diabetes patients only.	For patients aged 18 years and older who have type 1 or type 2 diabetes. Basal insulin titration is for type 2 diabetes patients only.
Environment of Use	Home under direction of HCP and Clinic	Home under direction of HCP and Clinic
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. BlueStar Rx is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar 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. BlueStar Rx is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes

Feature	BlueStar (Subject Device)	BlueStar Rx (Predicate – K193654)
	automatically receives insulin dose related data when connected to a compatible Tempo Smart Button device via wireless Bluetooth technology and has the ability to detect which doses are prime and which are injected insulin. BlueStar Rx analyzes, and reports glucose test results and supports medication adherence. In addition, BlueStar Rx provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. 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 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 IAP and configure it for patient-specific parameters. BlueStar Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.	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. The healthcare provider must activate the IAP and configure it for patient-specific parameters. BlueStar Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Feature	BlueStar (Subject Device)	BlueStar Rx (Predicate – K193654)
Indications for Use (OTC)	BlueStar® 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 is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar automatically receives insulin dose related data when connected to a compatible Tempo Smart Button device via wireless Bluetooth technology and has the ability to detect which doses are prime and which are injected insulin. BlueStar analyzes, and reports glucose test results and supports medication adherence. In addition, BlueStar provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. The software also allows for entry of other diabetes-related healthcare information and provides educational information. BlueStar is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.	The WellDoc BlueStar® 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 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.
Software Level of Concern	Major	Major

Feature	BlueStar (Subject Device)	BlueStar Rx (Predicate – K193654)
Operating Platform	iOS and Android patient software applications. Web-based HCP software application (browsers such as Internet Explorer, Chrome, Firefox, Safari and Edge.)	iOS, Android, and web-based patient software applications. Web-based HCP software application (browsers such as Internet Explorer, Chrome, Firefox, Safari and Edge.)
Basal Insulin Titration & Support	Yes Applies to BlueStar Rx only (see Note-1).	Yes Applies to BlueStar Rx only (see Note-1).
HCP supervision	Yes Initiate, manage the bolus insulin calculator and basal insulin titration parameters	Yes Initiate, manage the bolus insulin calculator and basal insulin titration parameters
Prescription Use	Yes Applies to BlueStar Rx only (see Note-1).	Yes Applies to BlueStar Rx only (see Note-1).
Bolus Insulin Calculator	Yes Applies to BlueStar Rx only (see Note-1).	Yes Applies to BlueStar Rx only (see Note-1).
Tracks residual bolus insulin to mitigate stacking	Yes	Yes
Accounts for insulin on board (IOB)	Yes	Yes
Carbohydrate tracking	Yes	Yes
Blood Glucose Tracking	Yes	Yes
Logbook	Yes	Yes
Reports, graphs	Yes	Yes
Reminders	Yes	Yes
Compatible with Insulin Pens	Yes (via Tempo Smart Button)	No
Prime vs. dose identification	Auto prompt with manual edit	No
Compatible with BGMs	Yes	Yes
Compatible with CGMs	Yes through API	Yes through API
Mode of wireless	Bluetooth	Bluetooth

Feature	BlueStar (Subject Device)	BlueStar Rx (Predicate – K193654)
connectivity with other devices		
Dosing Related Safety Notifications	Yes	Yes

Discussions of similarities and differences in Indications for Use statements:

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

- Devices use glucose value to calculate a recommended insulin dose in order to aid in optimal insulin management.
- Devices are used by similar patient population.
    - With the exceptions of receiving additional information from the TSB, identification of prime vs. injected insulin dose, limiting patient use to mobile devices, and removal of the term "blood" to account for usage with BGM and CGM devices, the subject device and predicate have identical indications for use.
    - Subject device's intended use population is a sub-set of the predicate's intended use population.
- BlueStar Rx in the subject device and predicate device are prescription use and for use under direction of HCP.
    - Both devices include a bolus insulin calculator. HCP provides patient specific parameters prior to use of calculator. Insulin dose is calculated for meals and corrections while accounting for insulin on board (IOB).
    - BlueStar Rx in subject device and predicate also includes identical basal insulin titration algorithms. HCP configures, initiates, and then oversees the insulin titration process.
- Information for diabetes management is provided in both devices.
- Neither of the devices are intended to be a substitute for professional clinical advice.

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

Discussions of similarities and differences in technological characteristics:

The technological characteristics between the subject device (BlueStar Rx) and the predicate (BlueStar Rx, K193654) are similar.

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

- Subject device and predicate device use similar mobile operating platforms (iOS, Android)
- Subject device and predicate device have logbook functionality with manual dose logging,

reports, graphs, reminders, carbohydrate tracking, and blood glucose tracking
- Subject device and predicate device are compatible with other devices such as BGMs, CGMs

The differences between the subject device and predicate are as follows:
Following modifications were made to the predicate to enable integration with *Tempo Smart Button*^{TM}:

- TSB integration in software user interface flow including - Registration and Onboarding, TSB pairing and connections
- Logbook function including display synced doses, prime detection
- Bolus insulin calculator
    - Allow HCP authorization of calculator within patient app (using a code)
    - Includes Lyumjev^{TM} (insulin lispro-aabc)
- Basal insulin titration
    - Alert patient if a bolus insulin dose is synced (recorded) and Suspend Insulin Adjustment Program (IAP).
- The predicate device's patient software application supports a web-based operating platform.
- Other modifications
    - Dosing, duplicate data, Bluetooth, and Jailbroken device related notifications

When evaluating the similarities and differences in technological characteristics, the reference device, InPen System (K160629), was also considered.

The similarities between the subject device and the reference device are outlined as follows:

- Subject device and reference device have automated dose transfer using Bluetooth wireless technology
- Subject device and reference device have prime (vs. dose) identification using algorithm that allows manual editing (or override)

The differences between the subject device and the reference device are outlined as follows:

- Reference device does not support basal insulins

In terms of technological characteristics, the subject device (BlueStar Rx), predicate device and reference device differ in certain minor details. However, those differences do not raise new or different 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).
Human Factors	• Human factors evaluation was conducted with the intended user populations of patients and healthcare providers. The human factors information provided in the submission confirms 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 (BlueStar and BlueStar Rx) has same intended use, similar indications for use and technological characteristics as those of the predicate device (BlueStar Rx, K193654) and reference device (InPen System, K160629).

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. BlueStar is substantially equivalent to the predicate cited.