



WellDoc, Inc.
Caroline York
Senior Vice President, Operations
10221 Wincopin Circle, Suite 150
Columbia, Maryland 21044

November 4, 2019

Re: K190013

Trade/Device Name: WellDoc BlueStar
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ, NDC
Dated: October 25, 2019
Received: October 28, 2019

Dear Caroline York:

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); 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,

Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K190013

Device Name
WellDoc® BlueStar®

Indications for Use (Describe)

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.

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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Indications for Use

510(k) Number (if known)
K190013

Device Name
WellDoc® BlueStar®

Indications for Use (Describe)

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 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.

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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K190013 510(k) Summary

Date of Summary Preparation: November 1, 2019
Name of Manufacturer: WellDoc, Inc.
Address: 10221 Wincopin Circle, Suite 150
Columbia, MD 21044
Contact Person: Kevin McRaith
Chief Executive Officer
Phone: (443) 692-3100
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Trade or Proprietary Name: WellDoc® BlueStar®
Common or Usual Name: Medical computers and software
Infusion pump accessories
Product Codes: MRZ, NDC
Regulation: 21 CFR 880.5725 – Accessories, Pump, Infusion
21 CFR 868.1890 – Calculator, Drug dose
Regulatory Class: II
Classification Panel: General Hospital
Predicate Device: K162532 (WellDoc® BlueStar® and BlueStar® Rx System)
Reference Device: K150910 (Accu-chek Connect Diabetes Management Application)

Device Description

WellDoc® BlueStar® 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, as cleared under K162532. Patients receive guidance on diabetes self-management and are encouraged to reach out to their healthcare team when needed. There are two versions of BlueStar® – BlueStar® and BlueStar® Rx – which differ in the availability of the insulin dose calculator, which is restricted to a prescription from a licensed HCP with prescribing authority.

BlueStar® and BlueStar® Rx are implemented through an enterprise such as a health plan or large physician group in tandem with a patient’s healthcare team and are comprised of the following applications:

- Enterprise Director Portal
- HCP Service
- Patient Mobile Application
- Patient Web Portal

The Enterprise Director application is used for administrative purposes. The HCP Service houses the Medication Reconciliation feature, which allows for the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage and frequency, by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider (cleared under K141273).

The Patient Web Portal and the Patient Mobile application have a similar feature set. Data (including blood glucose values, medications, carbohydrates, and activity) entered into these applications are stored in the database and can be retrieved for display in either application. Both applications require the initial web- or mobile-based registration before the patient can access them. On the patient applications (Mobile and Web), BlueStar® and BlueStar® Rx function as an (1) information repository (logbook and Personal Health Record) and (2) diabetes education resource (learning library and health tips) and provide (3) motivational, behavioral, and educational coaching based on real-time blood glucose values and trends, (4) a secure communication system (Message Center), (5) medication information (dose and schedule), and (6) workflow and decision support for healthcare providers.

In BlueStar® Rx, the patient web portal and mobile application also provide an insulin 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. This submission introduces Insulin on Board to be considered in the calculation. The insulin dose calculator is indicated for prescription-use only.

Furthermore, as cleared under K162225, BlueStar® and BlueStar® Rx have the ability to connect to the One Touch Verio Flex Blood Glucose Meter (K150214) 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 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. These modifications do not change the fundamental scientific technology of the device.

Indications for Use

The device has two (2) versions: over the counter and prescription.

OTC:

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.

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 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.

Intended Use

The intended use of the subject device is unchanged from the previously cleared version (K162352), and is as follows:

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 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.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	<u>Subject Device</u> The WellDoc BlueStar System	<u>Predicate Device</u> The WellDoc BlueStar System
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	K190013	K162532
Indications for Use	<p>OTC: 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.</p> <p>The BlueStar® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.</p> <p>Rx: BlueStar is indicated for use by healthcare providers (HCPs) and their adult 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 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</p>	<p>OTC: The WellDoc BlueStar® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have 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.</p> <p>The BlueStar® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.</p> <p>Rx: BlueStar® Rx is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older - who have 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</p>

	<p>of other diabetes-related healthcare information and provides educational information. The prescription version of 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.</p> <p>BlueStar® Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.</p>	<p>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 prescription version of 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.</p> <p>BlueStar® Rx is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.</p>
Prescription Only or Over the Counter	OTC, Rx	OTC, Rx
Intended Population	Patients with Type 1 or Type 2 Diabetes; Aged 18 and older	Patients with Type 2 Diabetes; Aged 21 and older
Environment of Use	Home or Clinic	Home or Clinic

Discussions of differences in Indications for Use statement

As compared to the previously cleared version, the subject device of this application proposes to make the following changes:

- Change the indications for use to include Type 1 diabetic patients to the user group;
- Change the indications for use to allow use in patients aged 18 and older (previously it was 21 years and older);
- Add Insulin on Board (IOB) to its insulin dose calculator function; and
- Add the ability to receive 3-hour delayed data from continuous glucose monitors via API for data visualization purposes only.

Discussions of differences in intended population

- Change the indications for use to include Type 1 diabetic patients to the user group;
- Change the indications for use to allow use in patients aged 18 and older (previously it was 21 years and older);

Discussions of differences in environment of use

The environment of use for the subject device is identical to the predicate device: home and clinic use.

Summary

The subject and predicate devices are both insulin dose calculators intended to be used by diabetic patients. The differences between the subject and predicate devices are focused on the intended patient population being expanded to include Type 1 diabetic patients and patients aged 18 and older, in addition to updates to the user interface; these changes do not raise different questions of safety or effectiveness. Performance data provided in the submission, including human factors, design, and labeling information, demonstrate substantially equivalent performance to the predicate. The data included participants from the new intended patient population and in conjunction with implemented labeling risk mitigation measures the device is equivalent to the predicate.

Moreover, as further demonstrated in the non-clinical testing, the different technological characteristics of adding the Insulin on Board feature and ability to connect to delayed data from CGM do not affect the safety and effectiveness of WellDoc BlueStar System.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	<u>Subject Device</u> The WellDoc BlueStar System K190013	<u>Predicate Device</u> The WellDoc BlueStar System K162532	<u>Reference Device</u> The ACCU-CHEK Connect Diabetes Management App K150910	<u>Comments</u>
Insulin Dose Calculator	Yes (Rx-only)	Yes (Rx-only)	Yes (Rx-only)	Same
Insulin on Board	Yes (Rx-only)	No	Yes (Rx-only)	See Comment 1
Connection to Blood Glucose Meter	One-Touch Verio Flex and CGMs (CGM for data visualization only)	One-Touch Verio Flex	ACCU-CHEK Aviva Connect blood glucose meter	See Comment 2

Discussions of differences in technological characteristics:

Comment 1: The addition of Insulin on Board to the Insulin Dose Calculator function available by prescription-only in BlueStar® Rx.

Both the subject device and reference device use a well-understood and accepted linear decay model to model the Insulin on Board decay. There are no notable differences with regards to this technological characteristic to a previously-cleared device.

Comment 2: The ability to receive three-hour delayed data from continuous glucose monitoring devices via API for data visualization purposes only.

The subject device does not use Bluetooth to connect to a Continuous Glucose Meter directly. There are no new questions with regards to software or cybersecurity. De Novo DEN140038 classified CGM secondary display regulation. BlueStar has complied per the special controls stated in 21 CFR 862.1350 .

Performance Testing

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

Software	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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
Electrical Safety	<ul style="list-style-type: none"> • N/A - This is a stand-alone software system. Electrical Safety testing was not required or completed.
EMC	<ul style="list-style-type: none"> • N/A
Wireless Coexistence & RF Wireless testing	<ul style="list-style-type: none"> • N/A
Accessory compatibility	<ul style="list-style-type: none"> • N/A
Battery testing	<ul style="list-style-type: none"> • N/A
Human Factors	<ul style="list-style-type: none"> • 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.
Reprocessing/Cleaning	<ul style="list-style-type: none"> • N/A
MR Safety	<ul style="list-style-type: none"> • N/A
Biocompatibility	<ul style="list-style-type: none"> • N/A

Clinical Tests

Not Applicable.

Conclusions

The differences between the predicate and the subject devices do not raise any new or different questions of safety or effectiveness. The WellDoc® BlueStar® and BlueStar® Rx System is substantially equivalent to WellDoc® BlueStar® and BlueStar® Rx System cleared under K162532 with respect to the indications for use, target populations, treatment method, and technological characteristics.