August 11, 2023

Welldoc, Inc.
Ian Cadieux
Head of Regulatory Affairs
10221 Wincopin Circle, Ste #150
Columbia, Maryland 21044

Re: K222888
Trade/Device Name: BlueStar® CGM insulin dose calculator
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QRX
Dated: September 22, 2022
Received: September 23, 2022

Dear Ian Cadieux:

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 M. 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)*
K222888

Device Name
BlueStar® CGM Insulin Dose Calculator

Indications for Use *(Describe)*
The BlueStar® CGM insulin dose calculator is software intended for the management of type 1 or type 2 diabetes in persons aged 18 years and older requiring fast-acting insulin. The BlueStar CGM insulin dose calculator allows patients to calculate a dose of bolus insulin for a given amount of carbohydrates, the most recent CGM glucose reading and rate of change, activity, and, optionally, insulin on board (IOB). The BlueStar CGM insulin dose calculator requires a prescription.

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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510(k) Summary

Date Prepared:	May 25, 2023
Name of Manufacturer:	WellDoc, Inc.
Address:	10221 Wincopin Circle, Suite 150 Columbia, MD 21044
Contact Person:	Ian Cadieux Head of Regulatory Affairs
Phone:	(619) 894-0873
Fax:	(443) 692-3099
Trade or Proprietary Name:	BlueStar® CGM insulin dose calculator
Common or Usual Name:	Continuous glucose monitor informed insulin dose calculator
Product Codes:	Classification: QRX
Regulation:	21 CFR 862.1358
Regulatory Class:	II
Classification Panel:	Clinical Chemistry
Predicate Device:	Omnipod 5 SmartBolus Calculator (K203772)
510k Number:	K222888

Device Description

The BlueStar® CGM insulin dose calculator is a software device module existing in the same mobile medical application as BlueStar® Rx (K203434), which is intended for the management of diabetes. When connected to a compatible integrated continuous glucose monitor (iCGM) and under authorization from a qualified healthcare provider, the BlueStar CGM insulin dose calculator allows patients to calculate a dose of bolus insulin for a given amount of carbohydrates, the most recent iCGM glucose reading and its rate of change, activity, and, optionally, insulin on board (IOB). Other patient-specific inputs from BlueStar Rx are used in the calculation of the recommended dose– specifically, duration of insulin action, insulin to carb ratio, correction factor, and target glucose. In addition to calculating specific dosing recommendations, the BlueStar CGM insulin dose calculator also provides coaching messages to assist the user in maintaining glucose within the target range.

The use of CGM inputs differentiates the BlueStar CGM insulin dose calculator from the insulin dose calculator included in the previously cleared BlueStar Rx, which uses blood glucose (BG) values from a BG meter using a "fingerstick" method. The CGM insulin dose calculator is intended to coexist with the BG insulin calculator function in the BlueStar Rx software application as the BG calculation may be necessary when CGM is unavailable or unstable or the CGM estimated blood glucose does not match how the user feels.

Indications for Use

The BlueStar® CGM insulin dose calculator is software intended for the management of type 1 or type 2 diabetes in persons aged 18 years and older requiring fast-acting insulin. The BlueStar CGM insulin dose calculator allows patients to calculate a dose of bolus insulin for a given amount of carbohydrates, the most recent CGM glucose reading and rate of change, activity, and, optionally, insulin on board (IOB). The BlueStar CGM insulin dose calculator requires a prescription.

Comparison to Predicate Device

The subject device matches the description of a Continuous Glucose Monitor Informed Insulin Dose Calculator – Insulin Therapy Adjustment Device described in 21 CFR 862.1358. A predicate device, the Omnipod 5 SmartBolus Calculator (K203772) of the same device type, shares substantially equivalent characteristics as the subject device. Both devices are intended for the management of diabetes. The indications for use of the subject device are within the indications of the predicate device, differing with respect to a narrower age indication in the subject device. Both devices are algorithmic software devices that calculate a recommended bolus insulin dose based on user-entered carbohydrates, most recent sensor glucose value, rate of change of the sensor glucose, insulin on board, and programmable correction factor, insulin to carbohydrate ratio, and target glucose value; more insulin is calculated when the sensor glucose trend is increasing, and less insulin is calculated when the sensor glucose trend is decreasing. The predicate device is a software component of a mobile medical application. Likewise, the subject device is a software component of a mobile medical application. Minor differences exist in the device settings that allow user-specific adjustments to the calculations and minor differences exist in the algorithms, which may result in minor differences in recommended insulin doses. The differences in device

settings and algorithms do not raise new questions regarding safety and effectiveness. Therefore, the BlueStar CGM insulin dose calculator is substantially equivalent to the predicate device.

Non-clinical Performance Testing

The following non-clinical 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 and FDA Guidance for General Principles of Software Validation (Jan 11, 2002).
Cybersecurity	Cybersecurity was evaluated per the FDA Guidance FDA Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (April 2022).
Human Factors	A human factors and usability engineering process was followed consistent with the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices (Issued February 3, 2016). Human factors validation was conducted with the intended user population and demonstrated safe and effective use of the BlueStar CGM insulin dose calculator.
Clinical Simulation	Clinical simulations were performed to evaluate the clinical validity of the dose recommendations across the range of input parameter combinations including inaccuracies from an interoperable input device.
Special Controls	The subject device was evaluated to ensure the Special Controls in 21 CFR 862.1358 are adequately addressed.

Clinical Testing

A clinical study was conducted on 27 adult subjects with either type 1 or type 2 diabetes who used a CGM and whose insulin regimen consisted of basal and mealtime (bolus) insulin. The primary endpoint of the study was to establish that the mean CGM glucose time in range (TIR) (defined as the percentage of time spent between 70 and180 mg/dL) of study participants using a version of the Bluestar mobile application integrated with the BlueStar CGM insulin dose calculator is not inferior to their baseline TIR determined from CGM data from 30 days prior. In addition, safety measures including time in hypoglycemia (obtained with CGM) and adverse events including hypoglycemic events were to be recorded. Data was collected for each subject for 30 days while using the BlueStar mobile app with the CGM insulin dose calculator. The statistical analysis of the study data showed that the mean TIR when using BlueStar with the CGM insulin dose calculator is not inferior to the baseline mean TIR prior to using the device. In

addition, there was no increase in time spent with glucose below 70 mg/dL and below 54 mg/dL in the subject populations. These data support the safety of the use of the Bluestar CGM insulin dose calculator.

Substantial Equivalence Conclusion

The subject device in this premarket notification, the Bluestar CGM insulin dose calculator, has the same intended use and similar indications for use and technological characteristics as those of the predicate device. Performance testing demonstrated that the device performs 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 CGM insulin dose calculator is substantially equivalent to the predicate device.