510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K222888

B Applicant

Welldoc, Inc.

C Proprietary and Established Names

BlueStar® CGM insulin dose calculator

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QRX	Class II	21 CFR 862.1358 - Insulin Therapy Adjustment Device	CH - Clinical Chemistry

E Purpose for Submission:

New Device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

III Device Description

The BlueStar® CGM insulin dose calculator is a software module that resides in the BlueStar Rx application (K203434). It requires input parameters and settings from an integrated continuous glucose monitor (iCGM) as well as inputs set by a healthcare provider and by the user. When used with a compatible iCGM, the BlueStar CGM insulin dose calculator can use sensor glucose values and trends to calculate a bolus of fast-acting insulin and provide coaching messages on implementing insulin boluses and suggestions on when to consume rescue carbohydrates. The BlueStar CGM insulin dose calculator cannot use blood glucose data to calculate an insulin bolus, but blood glucose from a self-monitoring blood glucometer (SMBG) can be used in a separate calculator to determine a fast-acting insulin bolus in the event iCGM data is not available was previously cleared in K203434.

The BlueStar® CGM insulin dose calculator uses an algorithm to calculate both insulin boluses and coaching messages. The inputs that influence insulin doses are CGM value and rate of change inputs are sourced from a compatible iCGM device while the user carbohydrates, exercise status, and logged insulin for insulin on board calculations (optional) are sourced from the user or caregiver. The duration of insulin action, insulin to carb ratio, correction factor, and target glucose are all set by the healthcare provider and are editable by the patient except for duration of insulin action.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod 5 SmartBolus Calculator

B Predicate 510(k) Number(s):

K203772

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222888	K203772
Device Trade Name	BlueStar® CGM insulin dose calculator	Omnipod 5 SmartBolus Calculator
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to calculate insulin boluses based on CGM values and/or other relevant information	same
Principle of operation	Algorithmic software device	same
General Device Characteristic Differences		
Device Outputs	Calculates a suggested bolus dose output, calculates insulin on board, and provides coaching messages	Calculates a suggested bolus dose output and calculates insulin on board
Age Range of Intended Users	18 years and older	6 years and older

V Standards/Guidance Documents Referenced:

- 21 Code of Federal Regulations 862.1358 – Insulin therapy adjustment device
- Applying Human Factors and Usability Engineering to Medical Devices (Guidance for Industry and Food and Drug Administration Staff, February 3, 2016)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Guidance for Industry and Food and Drug Administration Staff, May 11, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Guidance for Industry and Food and Drug Administration Staff, October 2, 2014)
- The 510(k) Program. Evaluating Substantial Equivalence in Premarket Notifications (Guidance for Industry and Food and Drug Administration Staff, July 28, 2014)
- Format for Traditional and Abbreviated 510(k)s (Guidance for Industry and Food and Drug Administration Staff, September 13, 2019)
- eCopy Program for Medical Device Submissions (Guidance for Industry and Food and Drug Administration Staff, April 27, 2020)
- Guidance for General Principles of Software Validation (Guidance for Industry and Food and Drug Administration Staff, January 11, 2002)
- Policy for Device Software Functions and Mobile Medical Applications (Guidance for Industry and Food and Drug Administration Staff, September 27, 2019)
- ISO 14971:2007 Medical devices – Application of Risk Management to Medical Devices
- IEC 62304 Ed. 1.1 2015 Medical device software – Software life cycle processes

- IEC 62366:2015 Medical Devices – Part 1: Application of Usability Engineering
- ANSI/AAMI HE75:2009 Human factors engineering – Design of medical devices
- NIST SP 800-30 Rev.1 Guide for Conducting Risk Assessments
- AAMI TIR57:2016 Principles for medical device security

VI Performance Characteristics (if/when applicable):

Summary of Clinical Testing:

A single arm, single site, prospective clinical study was conducted to evaluate the BlueStar Rx continuous glucose monitor insulin bolus calculator (BlueStar CGM-IDC) in patients with type 1 and type 2 diabetes. The study enrolled 27 evaluable subjects aged 18 and older that had been using the Dexcom G6 continuous glucose monitor (CGM) for 30 days prior to the start of the study and were users of both long-acting insulin and short-acting insulin. The single site study consisted of three visits and 30 days of daily use of the subject device use to administer short-acting bolus insulin:

- Visit 1: Participants received configured device and used it daily for 7 days
- Virtual Visit 2: Principal Investigator reviewed CGM data for the first week to assess if parameters of the calculator needed adjustment and participants continued use of calculator for 23 days
- Visit 3: Study concludes, and participants are returned to their standard of care

The primary objective of the study was to evaluate the safety of the CGM-informed dose calculator using continuous glucose meter metrics of time in range (TIR) of 70-180 mg/dL during the 30-day study compared with the prior 30 days of CGM use as a baseline. The clinical study CGM metric results are presented in the table below. In the 27 subjects enrolled in the combined age cohort of 18+ years old there were zero (0) deaths and zero (0) unanticipated adverse device effects (UADE), and one (1) serious adverse event (SAE) reported that occurred due to device use. There were thirteen (13) total hypoglycemia events reported with one (1) being indicated by the principal investigator as being due to a participant's incorrect estimation of carbohydrates with a meal. There were no non-serious adverse events reported.

Comparison of mean time in glucose ranges of baseline CGM with no insulin bolus calculator use versus CGM-informed dose calculator (BlueStar CGM-IDC) of intention to treat population (n=27)

Range (mg/dL)	% Time, Baseline [SD]	% Time, With CGM-IDC [SD]	% Difference
70-180	66.9 [12.47]	68.8 [17.67]	1.9
< 70	0.98 [1.07]	0.79 [0.81]	-0.19
< 54	0.18 [0.28]	0.12 [0.19]	-0.06
> 180	32.15 [12.66]	30.41 [17.49]	-1.74
≥ 250	5.85 [5.11]	6.27 [7.47]	0.42
≥ 300	1.30 [1.87]	1.66 [3.05]	0.36

In-Silico Testing:

A mathematical simulation of the possible input combinations as well as a simulated clinical study using virtual patients were used to assess potential edge cases (including physiologically improbable edge cases). The simulation data accounted for CGM point and trend errors. The simulated data supports the clinical validity of the subject device outputs.

Software:

The firm provided software documentation consistent with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005), and consistent with software with a major level of concern. Software documentation was acceptable.

Human Factors:

Human factors evaluation was conducted to assess whether users can perform all critical tasks associated with the new device. Subjects were representative of the device's intended use population.

VII Proposed Labeling:

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

VIII Conclusion:

The device is substantially equivalent to the predicate.