510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K252818

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom Smart Basal

D Regulatory Information

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

A 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 Dexcom Smart Basal insulin dose calculator is software intended for the management of type 2 diabetes in persons aged 18 years and older requiring long-acting insulin. This is not for use for patients on fast-acting insulin. The Dexcom Smart Basal insulin dose calculator calculates a dose of basal (long-acting) insulin using logged doses and glucose measurements from an integrated continuous glucose monitor (iCGM). The Dexcom Smart Basal insulin dose calculator requires a prescription and initial configuration by a healthcare provider.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

The Dexcom Smart Basal system is not intended to be used with automated insulin dosing (AID) systems or fast-acting insulin.

The Dexcom Smart Basal system is compatible with glargine U-100 insulin only. Only use glargine U-100, as it is the only insulin type tested and confirmed to be safe for use with the Dexcom Smart Basal system.

The Dexcom Smart Basal system is not recommended for use during pregnancy. The Dexcom Smart Basal system has not been tested with individuals who are pregnant.

III Device Description

The Dexcom Smart Basal System is a basal insulin (long-acting insulin) dose calculator intended for use by individuals with type 2 diabetes. It requires a prescription and initial configuration by a healthcare provider (HCP). The Smart Basal System is a software system designed to optimize and recommend basal insulin doses for Dexcom CGM App Users (patients) using their CGM data, insulin dose logs, and HCP-entered patient-specific treatment parameters. The Dexcom Smart Basal System is comprised of applications that initiate and manage the basal titration process for Dexcom CGM App Users with Type 2 diabetes who may benefit from long-term insulin treatment.

The Smart Basal System consists of cloud-based software components that function as a CGM-informed basal insulin dose calculator (subject device). The Smart Basal feature can be accessed via a module within a compatible CGM System mobile application for the patient to interact with (referred to as Host App), and a web-based user interface for the HCP (referred to as Host Portal).

The Dexcom Smart Basal System contains the following subject software components: Therapeutic Services and Therapeutic Portal. In addition, the Dexcom Smart Basal System utilizes a compatible Host App and Host Portal to interact with the patient and HCP respectively.

Therapeutic Portal and Host Portal are web-based applications. The Host Portal is a web-based application that directly interfaces with HCPs. The Therapeutic Portal is a server-based application that supports the creation, storage, and communication of the patient's treatment plan. Using the Therapeutic Portal (via Host Portal), HCPs create a basal treatment plan for patients that include patient-specific basal parameters, such as "initial dose" and "maximum dose" thresholds, and initiates the treatment for the particular patient (called an "episode"). Therapeutic Portal communicates directly with the Host App to initialize the system and to communicate dose recommendations generated by Therapeutic Services.

The Host App is the mobile app that hosts the basal therapy optimization module that interfaces with the patient. A compatible Dexcom CGM mobile app functions as the Host App for the Smart Basal System. The mobile app collects Estimated Glucose Values (EGVs) from the wearable CGM sensor and transmits EGV data to Therapeutic Services. Values for patient-administered basal insulin doses entered in the Host App are communicated to Therapeutic Services as well.

Therapeutic Service is a server-based software component that includes the algorithm for basal insulin dose recommendations. Using the EGV values and insulin dose logs from the Host App, together with the patient's basal treatment plan from the Host Portal (via Therapeutic Portal), Therapeutic Services then generates a daily dose recommendation. This daily dose recommendation is sent to the Host Portal (via Therapeutic Portal) and the Host App (also via Therapeutic Portal) which the patient consults to administer and log the next dose. The daily basal insulin dose recommendation continues until one of the following criteria is met: 1) Therapeutic Services determines the basal optimization is complete; 2) the HCP stops the patient's treatment using the Therapeutic Portal (via Host Portal), 3) the patient stops the treatment via the Host App, or 4) the days in a titration episode for the patient reaches a fixed time limit.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

BlueStar CGM insulin dose calculator

B Predicate 510(k) Number(s):

K222888

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252818	K222888
Device Trade Name	Dexcom Smart Basal System	BlueStar CGM insulin dose calculator
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to calculate insulin doses based on CGM values and/or other relevant information	Same
Principle of operation	Algorithmic software device	Same
Age range of intended users	18 years and older	Same
Display to user	Calculated doses via mobile application and use a web-based portal for healthcare providers	Same

General Device Characteristic Differences		
Insulin type	Long-acting insulin	Fast-acting insulin
Diabetes type	Type 2 diabetes	Type 1 or Type 2 diabetes
Data inputs	CGM values and historic data, initial configuration from HCP, daily basal insulin log	Same and also carbohydrate information
Titration episode length	Up to 90 days, unless terminated by the HCP or patient	Continuously as long as the patient is using the same bolus insulin

V Standards/Guidance Documents Referenced:

ANSI/AAMI/ISO 14971:2019 Medical devices – Applications of risk management to medical devices

ANSI/AAMI/IEC 62304:2006/A1:2016 Medical device software – Software life cycle processes [Including Amendment 1 (2016)]

ANSI/AAMI/IEC 62366-1:2015 + AMDI:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1

ANSI/AAMI HE75:2009/(R)2018 Human factors engineering – Design of medical devices

VI Performance Characteristics:

Clinical Testing

A prospective, multi-center, single-arm study was conducted at two sites in the US to evaluate the safety and effectiveness of the Dexcom Smart Basal System in adult patients with type 2 diabetes. The study enrolled 14 participants aged 18 years and older who were initiating or optimizing glargine U-100 insulin therapy.

The study was conducted in four phases: Phase 1 involved a 10-day run-in period with CGM training and baseline data collection. Phase 2 consisted of 10-35 days of active titration where HCPs reviewed daily algorithm-generated dose recommendations and communicated them to participants. Phase 3 involved 20 days of continued dosing with the final recommended dose while collecting outcome data. Phase 4 was a single day for post-titration assessments.

Of note, as the system used in the clinical study was an early version of the submitted device, DexBasal, there was no user-facing interface at that time. Instead, the HCP would add the subject to the web portal and specify the treatment plan. Each day, the clinical staff used the HCP web

portal to review the system's recommended dose for glargine U-100, modify the dose if necessary, and communicate the dose to participants. Participants were instructed to log the provided dose into the Dexcom G7 mobile application.

Among 401 total dose recommendations generated by the system, HCPs accepted 387 (96.5%) without modification. Fourteen recommendations (3.5%) were adjusted, with 13 of these adjustments due to a temporary API outage that prevented the system from receiving necessary input data, and one adjustment due to a patient logging error (double basal logged) that triggered a 0-unit recommendation that the HCP overrode

The primary objective of the study was to evaluate the safety and effectiveness of the CGM-informed dose calculator for recommending doses of basal insulin using CGM metrics of time in range (TIR) of 70-180 mg/dL during the study compared to the 10-day run-in period. The clinical study CGM metric results are presented in the table below. Of the 14 subjects, over 35 days, 5 subjects reached "completion" with a safe and effective dose (positive termination of the device), 4 were estimated to be within 5 days of completion, 2 hit their HCP's maximum dose limit, 1 hit the algorithm maximum dose limit (1 u/kg), and 2 may or may not have reached completion. There were no reported adverse events due to use of the device. There was also no severe hypoglycemia, DKA, or HHS events. There was 1 psychiatric hospitalization unrelated to use of the device.

Summary of 10-day G7 CGM Metrics – All subjects (N = 14)

Range (mg/dL)	% Time, Baseline, Mean (SD)	% Time, Post-Titration, Mean (SD)	% Difference, Mean (SD)	% Difference, Median (Q1, Q3)	P-value*
70-180	30.8 (24.4)	51.5 (22.1)	20.7 (23.0)	16.0 (2.5, 43.7)	0.0017
< 54	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0, 0.0)	-
< 70	0.0 (0.1)	0.1 (0.2)	0.1 (0.2)	0.0 (0.0, 0.1)	-
> 180	69.2 (24.5)	48.4 (22.2)	-20.8 (23.1)	-15.9 (-43.7, -2.5)	0.0017
> 250	34.5 (33.8)	18.1 (22.7)	-16.4 (26.4)	-8.4 (-20.2, 0.6)	0.0085

*Wilcoxon Signed-Ranks Test was used

For the 3 subjects who initiated basal insulin during this study, average TIR increased from 16.8% to 65.7%, average time above 180 mg/dL decreased from 83.2% to 34%, and the average time below 70 mg/dL was unchanged (0.0%) during the study. For all subjects, overnight (12:00 am – 6:00 am) CGM metrics showed an average TIR increase from 43.7% to 67.0%, average time above 180 mg/dL decreased from 56.2% to 32.7%, and the average time below 70 mg/dL was unchanged (0.1%).

<u>In-Silico Testing</u>

After the clinical study, the sponsor made changes to the dosing algorithm to enhance device performance and robustness, particularly in edge/patient use error cases. The changes were tested in an *in silico* clinical trial re-run validation test to assess how changes made to the algorithm used in the clinical study impact the recommended doses compared to the recommended doses in the clinical study algorithm. Changes made to the clinical study algorithm between use in the clinical study and commercialization do not affect the safety and effectiveness of the device.

The sponsor also performed a simulation to evaluate the impact of CGM sensor bias from the 10-day G7 CGM, used in the clinical study to support this device validation, and the 15-day G7 CGM, representing the intended CGM device for Smart Basal commercialization, on the glycemic safety and effectiveness of dose recommendations generated by this device. The validation considered systemic bias in estimated glucose values, which is a source of input error relevant to the Smart Basal algorithm's operation. The validation results demonstrate that the Smart Basal algorithm maintains safe and effective dose recommendations when used with the 15-day G7 device.

Software

Dexcom provided software documentation consistent with FDA Guidance for the Content of Premarket Submissions for Device Software Functions and consistent with software with a major level of concern. Software documentation was acceptable.

Cybersecurity

Dexcom provided cybersecurity documentation consistent with FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Cybersecurity documentation was acceptable.

Human Factors

A human factors study was conducted to assess if representative users of the Smart Basal System can safely use the system under representative conditions. Study subjects were representative of the device's intended use population (healthcare providers and patients with type 2 diabetes).

VII Proposed Labeling:

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

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.