Dexcom, Inc.
Dhara Sanjaykumar Desai
Senior Regulatory Affairs Specialist
6340 Sequence Drive
San Diego, California 92121

November 18, 2025

Re: K252818
Trade/Device Name: Dexcom Smart Basal
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin therapy adjustment device
Regulatory Class: Class II
Product Code: QRX
Dated: September 4, 2025
Received: September 4, 2025

Dear Dhara Sanjaykumar Desai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252818

Device Name
Dexcom Smart Basal

Indications for Use *(Describe)*
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.

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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dexcom

Dexcom, Inc. | Corporate Headquarters
6340 Sequence Drive | San Diego, CA 92121
888.738.3646 | dexcom.com

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K252818
Prepared on: 2025-11-13

Contact Details

Applicant Name	Dexcom, Inc.
Applicant Address	6340 Sequence Drive, San Diego, CA 92121, United States
Applicant Contact Telephone	1 (608) 332-8135
Applicant Contact	Ginny Hu
Applicant Contact Email	ginny.hu@dexcom.com

Correspondent Name	Dexcom, Inc.
Correspondent Address	6340 Sequence Drive, San Diego, CA 92121, United States
Correspondent Contact Telephone	1 (213) 285-7353
Correspondent Contact	Dhara Sanjaykumar Desai
Correspondent Contact Email	dharasanjaykumar.desai@dexcom.com

Device Name

Device Trade Name	Dexcom Smart Basal
Common Name	Continuous Glucose Monitor Informed Insulin Dose Calculator
Classification Name	Insulin Therapy Adjustment Device
Regulation Number	21 CFR 862.1358
Product Code	QRX

Legally Marketed Predicate Device:

Predicate #	K222888
Predicate Trade Name	BlueStar CGM insulin dose calculator
Product Code	QRX

dexcom

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888.738.3646 | dexcom.com

Device Description Summary:

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 Dexcom Smart Basal system is designed to optimize and recommend basal insulin doses for patients who use compatible Dexcom CGM systems. The Dexcom Smart Basal system produces daily basal dose recommendations using the patients' 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 patients with type 2 diabetes who may benefit from long-term insulin treatment.

The Dexcom Smart Basal system consists of a cloud-based long-acting insulin dose calculator, a patient facing module within a compatible CGM system mobile application, and a web-based provider-facing user interface.

The purpose of this 510(k) submission is to introduce Dexcom Smart Basal system, supporting compliance with Special Controls as defined in 21 CFR 862.1358 for a Continuous Glucose Monitor (CGM) Informed Insulin Dose Calculator.

Intended Use/Indications 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.

Comparison of Technological Characteristics with the Predicate Device:

Feature/Function	Dexcom, Inc Dexcom Smart Basal (Subject Device)	Welldoc, Inc BlueStar® CGM Insulin Dose Calculator (K222888) (Predicate Device)
Indications 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	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,

Feature/Function	Dexcom, Inc Dexcom Smart Basal (Subject Device)	Welldoc, Inc BlueStar® CGM Insulin Dose Calculator (K222888) (Predicate Device)
	from an integrated continuous glucose monitor (iCGM). The Dexcom Smart Basal insulin dose calculator requires a prescription and initial configuration by a healthcare provider.	and optionally, insulin on board (IOB). The BlueStar CGM insulin dose calculator requires a prescription.
Rx or OTC	Rx	Rx
Age Range of Intended Users	18 yrs and up	18 yrs and up
Principle of Operation	Algorithmic software device	Algorithmic software device
Device Inputs	Requires data from an integrated continuous glucose monitor (iCGM) device, input parameters set by a healthcare provider, and logged insulin doses by the patient	Requires data from an integrated continuous glucose monitor (iCGM) device, input parameters set by a healthcare provider, and additional settings set by the patient
Device Outputs	Calculates a suggested daily basal dose output Provides a titration episode state that informs the patients of program completion	Calculates a suggested bolus dose output, calculates insulin on board, and provides coaching messages
Verification & Validation	• Software Verification and Validation • Clinical Validation • Human Factors Validation • Benchtop Scenario Testing • Cybersecurity	• Software Verification and Validation • Clinical Validation • Human Factors Validation • In-Silico Testing • Cybersecurity

Non-Clinical and Clinical Performance Testing

The Dexcom Smart Basal system was verified and validated according to Dexcom's internal design control processes and in accordance with special controls for continuous glucose monitor informed insulin dose calculators. These testing demonstrated that the Dexcom Smart Basal system performed accordingly to its specifications and that the technological and performance criteria are comparable to the predicate device.

The non-clinical and clinical testing for the Dexcom Smart Basal system is similar to that of the predicate device (K222888). Like the predicate, the subject verification and validation activities included the following:

Software	Software verification and validation testing was conducted to confirm that the Dexcom Smart Basal system performed in accordance with established specifications, IEC 62304 and FDA Guidance document "Guidance for the Content of Premarket Submissions for Device Software Functions," June 14, 2023. Evaluation activities included code review, unit, system integration, and system level testing which verified functionality of the device against established software requirements. Results of the software executed protocols for the Dexcom Smart Basal system are acceptable for their intended use.
Clinical Validation	A clinical study was conducted to validate the safety and effectiveness of the Dexcom Smart Basal system. The study enrolled subjects with type 2 diabetes who use a CGM and whose insulin regimen consisted of basal insulin only. The clinical study design is similar to that of the validation study of the predicate device (K222888). Like the predicate, the subject device validation study demonstrates that the mean CGM glucose time in range (TIR) (defined as the percentage of time spent between 70 and 180 mg/dL) is not inferior to the baseline TIR determined prior to start of titration using the subject. In addition, safety measures including moderate and severe hypoglycemia, diabetic ketoacidosis (DKA), and hyperosmolar hyperglycemic state (HHS) adverse events were recorded. The statistical analysis of the study data showed that average TIR post-titration is not inferior to the baseline average TIR pre-titration. There was statistically significant improvement in average TIR observed in the study cohort. There were no device-related adverse events. This data demonstrated that there were no new types of adverse events related to the use of CGM informed insulin dose calculators with basal insulin identified and supports the safety and effectiveness of the use of the Dexcom Smart Basal system for basal insulin dose recommendations.
Human Factors	Human factors and usability testing of the Dexcom Smart Basal system was conducted to evaluate the intended user population on their ability to operate the Dexcom Smart Basal system without use errors, close calls, operational difficulties or intentional misuse, and on their ability to demonstrate comprehension by responding to specific knowledge-based questions. Human Factors testing was conducted in accordance with: • Design considerations for Devices intended for Home Use, Guidance to FDA Staff and Industry, November 24, 2014 • Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016 • IEC 62366-1:2015/AMD 1:2020: Medical devices – Part 1: Application of Usability Engineering to Medical Devices

	• ANSI/AAMI HE75:2009/(R) 2018 – Human Factors Engineer, Design of Medical Devices The critical, essential and frequently performed tasks were evaluated to demonstrate safe and effective use of the Dexcom Smart Basal system and were identified through a use-related risk analysis (URRA), which identified critical tasks solely based on the Severity of harm and included tasks resulting from known-use problems and hazards analysis. An analysis of hazards and risks was conducted on the Dexcom Smart Basal system to determine safety risks associated with use of the system. Results of the human factors study support that the intended users can use the Dexcom Smart Basal system safely and effectively.
Benchtop Scenario Testing	Additional non-clinical validation testing was performed on the Dexcom Smart Basal algorithm across various off-nominal conditions and clinical scenarios, including variations in patient dosing behavior and physiology, to assess potential edge cases related to foreseeable misuse. Results support the clinical validity of the Dexcom Smart Basal system outputs in the form of daily basal insulin dose recommendations.
Cybersecurity	Dexcom has provided cybersecurity risk management documentation for the Dexcom Smart Basal system that includes analysis of confidentiality, integrity, and availability for data, information and software related to the Dexcom Smart Basal system in accordance with the FDA Guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (June 26, 2025). For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality, integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested. In addition, Dexcom has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device software and components are malware free.
Special Controls	The subject device was evaluated to ensure the Special Controls in 21 CFR 862.1358 are adequately addressed.

Conclusions

The subject Dexcom Smart Basal system has the same intended use and similar indications for use and technological characteristics as those of the predicate device as discussed above. Dexcom provided performance testing within this premarket notification to demonstrate that the subject device performs as intended and in conformance to 21 CFR 862.1358 special controls for Insulin Therapy Adjustment Devices. The differences between the subject and predicate device

do not raise any new or different questions of safety or effectiveness, therefore, the subject Dexcom Smart Basal system is substantially equivalent to the predicate device.