April 24, 2026

Tandem Diabetes Care, Inc.
Geena George
Regulatory Affairs
12400 High Bluff Drive
San Diego, CA 92130

Re: K260429
Trade/Device Name: Control-IQ+ technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI
Dated: February 10, 2026
Received: February 10, 2026

Dear Geena George:

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
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OHT7: Office of In Vitro Diagnostics
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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)*
Control-IQ+ technology

Device Name

K260429

Indications for Use *(Describe)*

Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

Control-IQ+ technology is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy.

Control-IQ+ technology is intended for single patient use and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Company	Tandem Diabetes Care, Inc 12400 High Bluff Drive San Diego, CA 92130
Prepared	10 February 2026
Contact	Amulya Mallavarapu Sr. Regulatory Affairs Specialist +1 (857) 452 0773 amallavarapu@tandemdiabetes.com
Trade Name	Control-IQ+ technology
Common Name	Interoperable Automated Glycemic Controller
Classification Product Code	QJI
Classification Name	Interoperable Automated Glycemic Controller
Regulation Number	21 CFR 862.1356
Device Class	Class II
Predicate Device	K250798, Control-IQ+ technology

I. Device Under Review

The Subject Device, Control-IQ+ technology ("Control-IQ+") is a software-only device intended for the management of type 1 and type 2 diabetes mellitus. The device controls insulin delivery from a compatible alternate controller enabled insulin pump (ACE pump) based on inputs provided by a compatible integrated continuous glucose monitor (iCGM) and inputs provided by the user (e.g., carbohydrate intake, exercise, and sleep schedule). Control-IQ+ technology is meant to be installed on a compatible ACE pump.

Control-IQ+ technology has three different modes: Normal, Sleep, and Exercise. The glucose targets are not individually customizable in these modes but can change based on the mode selected. During Normal mode, Control-IQ+ technology aims to control glucose within a target range of 112.5 – 160 mg/dL, during Sleep mode the target range is 112.5 – 120 mg/dL, and during Exercise mode the target range is 140 – 160 mg/dL.

Control-IQ+ technology includes an integrated feature whereby iCGM values are automatically populated into the glucose field of the integrated bolus calculator when Control-IQ+ technology is active (i.e., the device is operating in closed-loop mode). This feature is disabled when Control-IQ is turned off.

Control-IQ+ technology requires users to input their weight and their total daily insulin requirement, which should be established with the help of a health care provider before using the device.

II. Intended Use/ Indications for Use

Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

Control-IQ+ technology is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy.

Control-IQ+ technology is intended for single patient use and requires a prescription.

III. Technological Characteristics Compared to Predicate Device K250798

	Predicate Device K250798	**Subject Device**
Intended Use/ Indications for Use	Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater. Control-IQ+ technology is intended for single patient use and requires a prescription.	Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater. **Control-IQ+ technology is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy**.

	Predicate Device K250798	Subject Device
		Control-IQ+ technology is intended for single patient use and requires a prescription.
Pump Type	An Alternate Controller Enabled Infusion Pump	Identical
Prescription Use	Prescription is required.	Identical
Compatible Insulins	NovoLog U-100 insulin Humalog U-100 insulin Lyumjev U-100 Insulin	Identical
Profile Delivery	When the predicted CGM value is within the target range, the pump will deliver insulin at the rate determined by the active Personal Profile settings. The user's profile basal rate may be set as high as 15 units/hr when Control-IQ is off and when Control-IQ is enabled same basal rate is applied.	Identical
Basal Rate Range	The Personal Profile correction factor is used to determine the predicted basal rate limits of 10 to 600 mg/dL per unit insulin.	Identical
Basal Attenuation	When Control-IQ+ technology predicts that the sensor glucose value will be at or below the target range 30 minutes in the future, the rate of insulin delivered will begin to decrease to attempt to keep glucose within the target range.	Identical
Automatic Correction bonus	The upper limit for the automatic correction bolus is 600 mg/dl per unit insulin.	Identical
Body Weight Setting Range	20 lbs (9kg)-440 lbs (200 kg)	Identical
Total Daily Insulin Setting Range	User setting of 5 units/day - 200 units/day	Identical
Extended Bolus	Up to 8-hour duration while Control-IQ+ is extended or disable and extended boluses are uninterrupted when enabling Control-IQ+.	Identical
Temporary Basal Rate	Temp Rates can be enabled without turning Control-IQ+ technology off.	Identical

IV. Overview of Non-Clinical Performance Tests

Appropriate testing was performed to confirm the Subject Device met specified requirements and performed as intended. See summaries below.

Usability/Human Factors:

No new Usability/Human Factors testing was performed to support this 510(k) Notification.

Software Verification and Validation:

No new software testing was performed to support this 510(k) Notification.

Insulin Compatibility and Biocompatibility:

No new insulin compatibility or biocompatibility testing was required for this 510(k) Notification.

Special Controls:

Evaluation and adherence to the Special Controls of the Predicate Device (K250798) demonstrates continued assurance of the safety and effectiveness of the Subject Device.

Clinical Testing:

A pivotal study, "Closed-loop Insulin delivery by glucose Responsive Computer algorithms In Type 1 diabetes pregnancies (CIRCUIT)", was conducted to evaluate the safety and effectiveness of using Control-IQ technology in pregnancy complicated by type 1 diabetes. In this randomized controlled trial, 91 pregnant women with pre-existing type 1 diabetes, ages 18 to 45 years old, were enrolled before 14 weeks gestation at 14 clinical sites in Canada and Australia. Participants randomized to Control-IQ technology started the system before 16 weeks gestation. The primary efficacy endpoint was glycemic control as reflected by percent glucose time-in-range (63-140 mg/dL) per day assessed by CGM glucose measurement (16 weeks until 34 weeks 6 days gestation) compared between groups.

Conclusion:

The Subject Device serves the same function as the Predicate Device. Furthermore, the Subject Device performs insulin therapy functions that are the same as that of the Predicate Device. The required technical documentation provided in this 510(k) demonstrates the Subject Device is as safe and as effective as the Predicate Device. Therefore, the Subject Device has been evaluated to be substantially equivalent to the Predicate Device and does not raise new or different questions of safety or effectiveness.