May 21, 2025

Tandem Diabetes Care, Inc.
Miriam Chan
Principal Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K250798
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: March 14, 2025
Received: March 14, 2025

Dear Miriam Chan:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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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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.

Submission Number *(if known)*

K250798

Device Name

Control-IQ+ technology

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 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.

510(k) Summary

Company	Tandem Diabetes Care, Inc 12400 High Bluff Drive San Diego, CA 92130
Prepared	March 07, 2025
Contact	Miriam Chan Principal Regulatory Affairs Specialist mchan@tandemdiabetes.com +1(858)202-6553
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	K243823, 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 single patient use and requires a prescription.

III. Technological Characteristics Compared to Predicate Device K243823

	Predicate Device K243823	**Subject Device**
Indications for Use/ Intended 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.	Identical

	Predicate Device K243823	Subject Device
Pump Type	Alternate controller enabled insulin pump	Identical
Classification	21 CFR 862.1356	Identical
Product Code	QJI	Identical
Compatible Insulins	Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin	Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin **Lyumjev U-100 Insulin**
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 Bolus	The upper limit for the automatic correction bolus is 600 mg/dL per unit insulin.	Identical
Body Weight Setting Range	20 lbs (9 kg) – 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 enabled or disabled 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 and 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.

Special Controls:

Evaluation and adherence to the Special Controls of the Predicate Device (K243823) demonstrates continued assurance of the safety and effectiveness of the Subject Device.

Clinical Testing:

A pivotal study, "Safety Evaluation of an Advanced Hybrid Closed Loop System Using Lyumjev with the Tandem t:slim X2 with Control-IQ in Adults, Adolescents and Children with Type 1 Diabetes (TL1)", was conducted to evaluate the safety and effectiveness of using Lyumjev with Control-IQ+ technology. Tandem performed a single-arm prospective safety trial that included 179 participants with type 1 diabetes (70 in adult cohort, ranging in age from 18-75 years old, and 109 in pediatric cohort, ranging in age from 6-17 years old) who were experienced users of the Control-IQ AID system.

The protocol consisted of two periods: ~16-day Humalog Lead-in Period and 13-week Lyumjev Treatment Period. The primary trial endpoints were related to safety, comparing the frequency of severe hypoglycemia and DKA events to the reported frequencies from the T1D Exchange clinic registry.

Conclusion:

The Subject Device has the same intended use and indications as the Predicate Device. The clinical study demonstrated that the use of Lyumjev with t:slim X2 insulin pump with Control-IQ technology was well tolerated with few adverse effects and no increase in hypoglycemia. Rates of severe hypoglycemia and DKA were lower

than in the T1D Exchange clinic registry data, with the statistical comparison meeting the prespecified success criteria. Therefore, the trial data demonstrates that Lyumjev with the t:slim X2 insulin pump with Control-IQ technology is safe and effective in patients with Type 1 diabetes 6 years of age and greater. 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.

V. Predetermined Change Control Plan

This submission included a predetermined change control plan (PCCP) that was reviewed and authorized by FDA for implementation of the proposed labeling modifications upon clearance of a compatible ACE pump. The change to Control-IQ+ Technology labeling will not be implemented prior to clearance of a compatible ACE pump submission. The PCCP outlines that the labeling modifications will match the cleared compatible insulins for both the ACE Pump and the iAGC.

The PCCP also defines the test methods and validation requirements to implement labeling changes per Tandem's Quality Management System. Following implementation new users will receive the physical Quick Start Guide upon receipt of their corresponding device and the new User Guide and Quick Start Guide will be available electronically or may be provided physically upon request. Existing users will be notified one of two ways. They will have the option to electronically download or request a printed version of the Quick Start Guide and User Guide, which will contain these labeling updates. Or be notified via email that an additional insulin has been approved for use with their device, and this communication will also include a link to download the Quick Start Guide and User Guide that contain the updated labeling.