November 3, 2023

Tandem Diabetes Care, Inc.
Christin Dunn
Senior Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K232382
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: August 7, 2023
Received: August 8, 2023

Dear Christin Dunn:

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 (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 located 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.

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232382

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.

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.

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510(K) SUMMARY FOR K232382

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for Control-IQ Technology is provided below:

Submitter Information

Name	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130 Phone: 858-366-6900
Applicant Contact	Christin Dunn Senior Regulatory Affairs Specialist Phone: 858-401-1641 cdunn@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Secondary Contact	Lan Herrington Director, Regulatory Affairs (858) 255-6378 LHerrington@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Date Prepared:	October 26, 2023

Device Identification

Trade name	Control-IQ Technology
Common name	interoperable automated glycemic controller
Regulation Name	interoperable automated glycemic controller
Classification number 21 CFR	862.1356
Product code	QJI
Regulatory class	II
Predicate devices	Control-IQ Technology (K200467)

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.

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

Description

Control-IQ technology (Control-IQ, the device) is a software-only device intended for the management of type 1 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 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 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, this range is changed to 112.5-120 mg/dL, and it is changed to 140-160 mg/dL during exercise mode.

Control-IQ technology includes an integrated feature whereby iCGM values are automatically populated into the glucose field of the integrated bolus calculator when the 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.

TANDEM Diabetes Care

Technological Characteristics Compared to Predicate Device

	PREDICATE DEVICE CONTROL-IQ TECHNOLOGY (K200467)	SUBJECT DEVICE (K232382)
Intended Use/Indication 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 6 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. Control-IQ technology is intended for single patient use and requires a prescription.

	Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin	
Pump Type	Alternate controller enabled insulin pump	Same
Classification	II	Same
Specific Drug/Biological Use	U-100 Insulin	Same
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, but is clipped to 3 units/hr when Control-IQ is enabled	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, the same basal rate is applied.
Basal Rate Range	The Personal Profile correction factor is used to determine the predicted basal rate limits of **10 to 200 mg/dL per unit insulin.**	The Personal Profile correction factor is used to determine the predicted basal rate limits of **10 to 600 mg/dL per unit insulin.**
Basal Attenuation	When Control-IQ technology	Same

	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.	
Automatic Correction Bolus	The upper limit for the automatic correction bolus is 200 mg/dL per unit insulin.	The upper limit for the automatic correction bolus is 600 mg/dL per unit insulin.
Body Weight Setting Range	55 lbs (25 kg) – 308 lbs (140kg)	20 lbs (9 kg) – 440 lbs (200 kg)
TDI Range	User setting of 10 units/day - 100 units/day.	User setting of 5 units/day - 200 units/day.
Extended Bolus	Up to 2-hour duration when Control-IQ is enabled, up to 8 hour duration when Control-IQ is disabled. Extended bolus delivery will be terminated when Control-IQ is enabled.	Up to 8-hour duration while Control-IQ is enabled or disabled and extended boluses are uninterrupted when enabling Control-IQ.
Temporary Basal Rates	In order to use Temp Rates, Control-IQ technology must be turned off	Temp Rates can be enabled without turning Control-IQ Technology off

Performance Data

Software verification and validation testing was performed in accordance with ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes.

Evaluation and adherence to the Special Controls (21 CRF 862.1356) demonstrate continued assurance of safety and effectiveness of the Subject Device.

Clinical Performance

A pivotal clinical study was conducted to evaluate the safety and effectiveness of Control-IQ Technology in individuals 2-5 years of age. This randomized controlled trial enrolled 102 subjects and the subjects were randomly assigned to Control-IQ or Standard Care (SC) in a 2:1 ratio. The subjects used the t:slim X2 insulin pump with Control-IQ Technology for 13 weeks. Upon completion of the 13 week study, participants could then enroll in an optional 13 week extension phase with the modified Control-IQ technology. Individuals assigned to the SC group were then moved to the Control-IQ group during this extension phase. The primary outcome of the study was CGM measured percent time in range 70-180 mg/dL.

Substantial Equivalence

The changes that have been made to the Control-IQ technology indications for use and software result in a product that is substantially equivalent to the predicate Control-IQ technology device. The intended use and indications for use have been previously cleared on the Tandem device except for the change in age from 6 to 2 years of age and greater. The changes to Control-IQ technology and the change in age are supported by clinical trial data that demonstrates that the devices are substantially equivalent. Moreover, software testing demonstrates that the device performs as expected and in a manner that is substantially equivalent to the predicate device. Thus, the modified Tandem Diabetes Care Control-IQ technology is substantially equivalent to the predicate Tandem Diabetes Care Control-IQ technology (K200467).