February 28, 2020

Tandem Diabetes Care, Inc.
Trevor Denbo
Sr. Manager, Regulatory Affairs
11075 Roselle Street
San Diego, California 92121

Re: K193483
Trade/Device Name: Basal-IQ Technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJS, NDC
Dated: December 16, 2019
Received: December 17, 2019

Dear Trevor Denbo:

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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193483

Device Name
Basal-IQ technology

Indications for Use *(Describe)*
Basal-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin based on iCGM readings and predicted glucose values.
Basal-IQ technology is intended for the management of diabetes mellitus in persons six years of age and greater.
Basal-IQ technology is intended for single patient use and requires a prescription.
Basal-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.
The bolus calculator is indicated for the management of diabetes by people with diabetes by calculating an insulin dose or carbohydrate intake based on user entered data.

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
Prepared: February 28, 2020

I.	**Company**	Tandem Diabetes Care, Inc
II.	**Contact**	Trevor J. Denbo, M.S., RAC Sr. Manager, Regulatory Affairs 858-224-6136
III.	**Product Trade Name**	Basal-IQ Technology
IV.	**Common Name**	
	Algorithm	Insulin Pump Algorithm
	Calculator	Bolus Calculator
V.	**Classification Name**	
	Algorithm	Interoperable Automated Glycemic Controller, Insulin Suspend
	Calculator	Predictive pulmonary-function value calculator
VI.	**Regulation Number**	
	Algorithm	21 CFR 862.1356
	Calculator	21 CFR 868.1890
VII.	**Device Class**	Class II
VIII.	**Classification Product Code**	
	Algorithm	QJS
	Calculator	NDC
IX.	**Predicate Device**	
	Algorithm	DEN190034, Control-IQ technology
	Calculator	K192841, InPen Dose Calculator

X. Description

Basal-IQ technology is a Predictive Low Glucose Suspend (PLGS) algorithm for the management of diabetes mellitus and is compatible with an Alternate Controller Enabled Infusion Pump (cleared under 21 CFR 880.5730)(ACE pump). Basal-IQ technology is only compatible with the Tandem t:slim X2 insulin pump (DEN180058). The Basal-IQ software and algorithm can receive interstitial sensor glucose values from a compatible iCGM system (cleared under 21 CFR 862.1355), via Bluetooth Low Energy (BLE) communication. Compatible iCGM systems are cleared and marketed separately from the Basal-IQ algorithm and are identified in device labeling.

Basal-IQ assesses glucose information provided by a paired iCGM and sends commands to a compatible ACE pump to temporarily suspend insulin delivery in cases of impending or detected low blood glucose. Every 5 minutes, the Basal-IQ feature assesses glucose information provided by the iCGM to predict whether glucose values will fall below 80 mg/dL in the next 30 minutes or detect if glucose levels are currently below 70 mg/dL. Under these conditions it will command the compatible pump to suspend insulin delivery; otherwise insulin delivery continues as normal. After insulin delivery is suspended, insulin delivery resumption is commended when the system detects glucose values begin to rise. A sustained suspension period when blood glucose is above the sensor suspend threshold is mitigated by a maximum suspend time where Basal-IQ will command resume insulin delivery after 120 minutes of suspension within a 150-minute window. The Basal-IQ technology uses CGM sensor readings to send commands to a compatible insulin pump to stop and resume insulin based on the current sensor value and a 30-minute future predicted value along with the following rules:

1. Insulin delivery is suspended if the current CGM sensor reading is less than 70 mg/dL
2. Insulin delivery is suspended if the glucose value is predicted to be less than 80 mg/dL in 30 minutes.
3. Basal insulin delivery is resumed once the current CGM sensor reading increases compared to the previous reading.
4. Basal insulin delivery will also be resumed if the 30-minute predicted CGM reading is above 80 mg/dL, even if the CGM reading has not increased compared to the previous reading.
5. Basal insulin delivery is resumed if insulin delivery has been suspended for 2 hours in a 2.5 hour window.

The software comprising the Basal-IQ algorithm also includes an insulin bolus dose calculator. This calculator is for assisting patients with Type 1 diabetes who use insulin pumps as their insulin delivery therapy. It is used to calculate insulin bolus doses of rapid acting U-100 insulin analogs (Humalog and Novolog).The bolus calculator is used with manually-inputted glucose values and pump insulin delivery data to generate bolus size recommendations.

XI. Indications for Use

Basal-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin based on iCGM readings and predicted glucose values.
Basal-IQ technology is intended for the management of diabetes mellitus in persons six years of age and greater.
Basal-IQ technology is intended for single patient use and requires a prescription.
Basal-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.

The bolus calculator is indicated for the management of diabetes by people with diabetes by calculating an insulin dose or carbohydrate intake based on user entered data.

Algorithm		
	Predicate Device (DEN190034, Control-IQ Technology)	**Subject Device** (Basal-IQ Technology)
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 14 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.	Basal-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin based on iCGM readings and predicted glucose values. Basal-IQ technology is intended for the management of diabetes mellitus in persons six years of age and greater. Basal-IQ technology is intended for single patient use and requires a prescription. Basal-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.
Includes Bolus Calculator	Yes	Yes
Auto-populates the Bolus Calculator with CGM values	Yes	Does not auto-populate any values into the Bolus calculator
Suspends Insulin when trending or found low CGM reading	Yes	Yes
Adjusts Insulin based on CGM readings	Yes	No
Adjusts or Boluses insulin based on high CGM readings	Yes	No
Intended Hardware Device	An Alternate Controller Enabled Infusion Pump (cleared under 21 CFR 880.5730)	Identical

Calculator		
	Predicate Device (K190487, InPen Dose Calculator)	**Subject Device** (K193483)
Indications for Use	The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes age 12 and older by calculating an insulin dose or carbohydrate intake based on user entered data. The device is indicated for use with NovoLog® or Humalog® U-100 insulin. For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use. For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.	The bolus calculator is indicated for the management of diabetes by people with diabetes by calculating an insulin dose or carbohydrate intake based on user entered data.
Prescription Use	Yes	Yes
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated the insulin pump in which the calculator is integrated.
Communication with insulin pumps	No	Yes, the insulin pump in which the calculator is integrated.
Wireless Connectivity	Bluetooth Low Energy (BLE)	No
Control or effect blood glucose measurements	No	No
Control or affect insulin delivery	No	No
Carbohydrate Calculator	Calculation based either on user entered carbohydrates, meal size estimation, or fixed meal doses.	Calculates carbohydrate intake based on user entered data
Manual data entry	Yes	Yes
Operating platform	Android	Pump

XII. Discussion of the Non-Clinical Testing

The t:slim X2 with Basal-IQ Technology, previously approved under P180008, contains the Basal-IQ Technology algorithm and calculator. No new non-clinical laboratory studies were needed for the separation from that system in order to be available for use on an Alternate Controller Enabled Infusion Pump (cleared under 21 CFR 880.5730). The Basal-IQ Technology is the same algorithm, and the t:slim X2 Bolus Calculator is the same calculator, as reviewed in P180008, therefore no additional testing was conducted.

Software modifications were made to the Tandem insulin pump to add the Basal-IQ Technology algorithm. Comprehensive verification and validation testing was conducted to confirm that the software used in the pump with Basal-IQ Technology met all specified requirements and performed as intended. Testing was carried out in accordance with FDA guidance "General Principles of Software Validation: Final Guidance for Industry and FDA Staff." Software development activities included establishing detailed software requirements, linking requirements with associated verification and validation activities, software code inspection, software code walkthrough, static code analysis, unit testing, and system testing to ensure that the software conforms to patient needs and intended uses.

A human factors study was conducted to confirm that the intended users can safely and effectively use the Basal-IQ Technology on the t:slim X2 Insulin Pump with Basal-IQ. This involved evaluating usability tasks, such as turning on/off PLGS, setting PLGS alerts, modifying PLGS alerts, and comprehending PLGS alerts. Any use difficulties did not represent serious use errors since users will still receive the other system alerts (e.g., CGM Low Alert, CGM High Alert, etc.). Therefore, results from the human factors study demonstrates users can safely and effectively use the PLGS feature of the t:slim X2 Insulin Pump.

XIII. Discussion of Clinical Testing

A total of 107 subjects with Type 1 Diabetes were enrolled at 4 sites in the United States (US). The study was a multi-center, randomized, at home, crossover design evaluation of subjects with type 1 diabetes. Study subjects enrolled were either insulin pump users, multiple daily injection of insulin (MDI) users, CGM naïve users (may be pump or MDI users), or experienced CGM users (may be pump or MDI users). Of the 107 subjects enrolled (over age f 6 years old) five subjects did not complete the study.

The 102 study subjects participated in a crossover design study, consisting of two 3- week periods with the t:slim X2 Insulin Pump with Basal-IQ (Basal-IQ enabled) used during one period and Sensor Augmented Pump (SAP) used during the other period. The crossover design study was preceded by a run-in phase in which participants received training using the study devices.

The performance data presented demonstrates that the Basal-IQ Technology of the already approved t:slim X2 Insulin Pump paired with the Dexcom G5 CGM (P140015/S020) can be used safely and that it functions as intended. The analysis of input specifications is adequate to assure reasonable safety and effectiveness when iCGM sensors are used with the system as well. Additionally, the performance data demonstrates that the Basal-IQ Technology functions as intended to stop and resume insulin delivery in response to low and high glucose levels, respectively.