510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K193483

B Applicant

Tandem Diabetes Care, Inc.

C Proprietary and Established Names

Basal-IQ Technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJS	Class II	21 CFR 862.1356 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Type of Test:

Not applicable

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

The pump is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by a healthcare provider
- Maintain sufficient diabetes selfcare skills
- See a healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize pump alerts.

The t:slim X2 pump, transmitter, and sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the components.

ONLY use U-100 Humalog or NovoLog with your pump.

Only U-100 Humalog and NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

ALWAYS use cartridges manufactured by Tandem Diabetes Care. Use of any other cartridge brand may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

IV Device/System Characteristics:

A Device Description:

Device 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.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

V Substantial Equivalence Information:

A Predicate Device Name(s):
Control-IQ Technology, InPen Dose Calculator

B Predicate 510(k) Number(s):
DEN190034, K190487

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193483	DEN190034
Device Trade Name	Basal-IQ Technology	Control-IQ Technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to automatically command suspension and resumption of basal insulin delivery from a compatible ACE pump based on glucose values from a compatible iCGM.	Intended to automatically command basal and bolus insulin delivery from a compatible ACE pump based on glucose values from a compatible iCGM.
Commands insulin suspension when trending or found low CGM reading	Yes	Same
Intended Hardware Device	An Alternate Controller Enabled Infusion Pump (cleared under 21 CFR 880.5730)	Same

General Device Characteristic Differences		
Auto-populates the Bolus Calculator with CGM values	No	Yes
Commands modified basal insulin delivery (beyond suspend) based on CGM readings	No	Yes
Commands adjusted basal or bolus insulin based on high CGM readings	No	Yes

	Predicate Device (K190487, InPen Dose Calculator)	**Subject Device** (K193483)
Intended Use/Indications For Use	For calculating an insulin dose based on user entered data.	For calculating an insulin dose based on user entered data.
Prescription Use	Yes	Yes
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with the insulin pump into which the calculator is integrated
Communication with insulin pumps	No	Yes, the insulin pump into which the calculator is integrated
Wireless Connectivity	Bluetooth Low Energy (BLE)	No
Control or effect blood glucose measurements	No	No
Control or effect insulin delivery	No	No
Carbohydrate Calculator	Calculation based either on user entered glucose and carbohydrates, meal size estimation, or fixed meal doses.	Calculations based on user entered carbohydrate and glucose data
Manual data entry	Yes	Yes
Operating platform	Android	Compatible insulin pump

VI Standards/Guidance Documents Referenced:

ISO 14971:2007: Medical Devices - Application of Risk Management to Medical Devices
FDA Recognition No: 5-40

ANSI/AAMI/IEC 62366-1:2015 Medical Devices – Application of usability engineering to medical devices

ANSI/AAMI HE75:2009 Human factors engineering, Design of medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Basal-IQ technology algorithm was previously approved as part of the T-slim X2 Insulin Pump with Basal-IQ Technology under P180008. Basal-IQ technology described in this submission consists of an identical insulin delivery algorithm and capacity for compatibility with an ACE pump and iCGM. No new non-clinical laboratory studies were conducted to validate the Basal-IQ technology separately from the system approved in P180008, in order to enable compatibility with and Alternate Controller Enabled (ACE) Infusion Pump (cleared under 21 CFR 880.5730) or integrated continuous glucose monitoring system (iCGM, under 21CFR 862.1355). The Basal-IQ technology is the same algorithm 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.

B Other Supportive Instrument Performance Characteristics Data:

Summary 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 the age of 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.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device and met the special controls for 21 CFR 862.1356.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.