February 15, 2022

Tandem Diabetes Care, Inc.
Ashley Reynolds
Regulatory Affairs Specialist II
11075 Roselle Street
San Diego, CA 92121

Re: K203234
Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG
Dated: August 27, 2021
Received: August 30, 2021

Dear Ashley Reynolds:

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,

Kellie B. Kelm, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203234

Device Name
t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)

Indications for Use *(Describe)*

The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.

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.

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510(k) Summary: K203234

Company	Tandem Diabetes Care, Inc 11075 Roselle Street San Diego, CA 92121
Prepared	7 February 2022
Contact	Ashley Reynolds Sr. Regulatory Affairs Specialist I +1 (858) 401-1725 areynolds@tandemdiabetes.com
Product Trade Name	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)
Common Name	Ambulatory Insulin Pump
Classification Name	Alternate Controller Enabled Infusion Pump
Regulation Number	21 CFR 880.5730
Device Class	Class II
Classification Product Code	QFG
Predicate Device	K201214 t:slim X2 Insulin Pump with Interoperable Technology

I. Purpose of Traditional 510(k)

Request to add the t:connect mobile app that can be wirelessly paired to the t:slim X2 Insulin Pump with Interoperable Technology (Predicate "The Pump") for the purposes of allowing limited control of bolus insulin therapy.

II. Indications for Use/Intended Use

The t:slim X2 Insulin Pump with Interoperable Technology (The Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.

III. Subject Device Description and Technological Characteristics

The t:connect mobile app can be wirelessly paired to the t:slim X2 Insulin Pump with Interoperable Technology, for the purposes of allowing limited control of bolus insulin therapy. The t:connect mobile app is available on iOS and Android compatible smartphones via the Apple Store® and Google Play Store®. When successfully paired with The Pump, users have the ability to perform the following via the t:connect mobile app:

- View The Pump therapy data, trends, alerts, alarms, notifications, and reminders as a secondary display.
- Program Correction Boluses, Bolus Override, and Food (Standard) Boluses.

- Terminate (Cancel or stop) all bolus types regardless of origin of bolus request being made on the t:slim X2 Insulin Pump or the t:connect mobile app.

Outside of programming and terminating boluses, the t:connect mobile app will have no other controlling action on The Pump.

Important: The Pump functions independently from the t:connect mobile app, therefore users can still view pump therapy data/trends, program requests, and cancel or stop boluses from their Pump. The t:connect mobile app does not control, or otherwise impact, any automated dosing algorithms of Interoperable Automated Glycemic Controllers such as Basal-IQ Technology (K193483) and Control-IQ Technology (K200467) to aid in diabetes management.

IV. Comparison with Predicate

	Predicate Device K201214	**Subject Device** K203234
Indications for Use/ IntendedUse	The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.	**Same**
Intended Hardware, Materials and Accessories	An Alternate Controller Enabled Infusion Pump (cleared under 21 CFR 880.5730)	**Same**

Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient based on health care provider recommendations.	**Same**
Prescription Use	Yes	**Same**
Compatible Interoperable Devices	The Pump is compatible with: • #DEN170088: Dexcom G6 Continuous Glucose Monitoring System or other compatible iCGM • #K193483: Basal-IQ Technology • #K200467: Control IQ Technology	**Same**
Includes Bolus Calculator	Yes	**Same** --- In addition, the t:connect mobile app will also include a built-in Bolus Calculator that has the same purpose and same functionas The Pump. The Pump shall send the t:connect mobile app information required to calculate boluses via the Bolus Calculator.
Pump Notifications, Alerts, and Alarms and Reminders Visible to User	The following are visible on The Pump: • Reminders • Alerts • Alarms • Notifications	**Same** --- The t:connect mobileapp will display The Pump Notifications, Alerts, and Alarms and Reminders. The t:connect mobile app cannot clear or alter notifications, alerts, alarms, and reminders. To clear or alter

		these, the user must go to The Pump. The t:connect mobile app will display specific alerts below: • Pump Connection Lost Alert- t:connect Mobile App • Incomplete Bolus Alert- t:connect Mobile App The t:connect mobile app will display the specific notification below: • Bolus in Progress on Pump
Logging records of critical events	Critical events logged by the system include: -A record of all drug delivery -Commands issued to the pump and pump confirmations - Device malfunctions -Alarms and alerts and associated acknowledgements -Connectivity events (e.g., establishment or loss of communications)	**Same** **----** All critical events remain stored by the system. In addition, The Pump will also log bolus requests and terminations (cancelling and stopping a bolus) from the t:connect mobile app. The t:connect mobile app will also log actions of bolus requests and bolus terminations.

V. Discussion of the Non-Clinical Testing

Human factors and software verification and validation tests were conducted to confirm that the Subject Device when paired with the t:connect mobile app, met specified requirements, and performed as intended.

Human factors validation testing was conducted to demonstrate the intended users can effectively use the Subject Device for its intended purpose in expected use environments. Usability tasks were evaluated in accordance to ANSI AAMI HE 75:2009 Human Factors Engineering- Design of Medical Devices, ANSI/AAMI/IEC 62366-1:2015 Medical devices - Part 1: Application of Usability Engineering To Medical Devices and Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices - February 3, 2016. The results from the human factors study demonstrates users can safely and effectively use the feature of the Subject Device.

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 level testing to ensure that the software conforms to patient needs and intended uses. Software verification and validation testing was carried out in accordance with ISO 14971:2019 Medical Devices - Application of Risk Management to Medical Devices, ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes, FDA guidance General Principles of Software Validation: Final Guidance for Industry and FDA Staff, Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff, February 9, 2015, and FDA guidance Multiple Function Device Products: Policy and Considerations- Guidance for Industry and Food and Drug Administration Staff, July 29, 2020.

In addition, Cybersecurity evaluations were carried out in accordance to Content of Premarket Submissions for Management of Cybersecurity in Medical Devices- Guidance for Industry and Food and Drug Administration Staff, both Final and Draft versions issued October 2, 2014 and October 18, 2018 respectively.

Evaluation and adherence of the Special Controls listed in the Predicate Device (K201214), demonstrate continued assurance of the safety and effectiveness of the addition of the t:connect mobile app as a compatible interoperable device.

VI. Discussion of Clinical Testing

No new clinical testing was required for this Traditional 510(k) Notification.

VII. Conclusions

The t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app) has been evaluated to be substantially equivalent to the Predicate and does not raise any new or different questions of safety or effectiveness.