June 4, 2020

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

Re: K201214
Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled (Ace) Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: May 5, 2020
Received: May 5, 2020

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,

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)*
k201214

Device Name
t:slim X2 insulin pump with interoperable technology

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.

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510(k) Summary
510(k) Number: k201214
Prepared: 04 May 2020

I.	**Company**	Tandem Diabetes Care, Inc. 11075 Roselle Street San Diego, CA 92121
II.	**Contact**	Ashley Reynolds, M.S. Regulatory Affairs Specialist II areynolds@tandemdiabetes.com +1 (858) 401-1725
III.	**Product Trade Name**	t:slim X2 Insulin Pump with Interoperable Technology
IV.	**Common Name**	Insulin Pump
V.	**Classification Name**	Alternate Controller Enabled Infusion Pump
VI.	**Regulation Number**	21 CFR 880.5730
VII.	**Device Class**	Class II
VIII.	**Classification Product Code**	QFG
IX.	**Predicate Device**	DEN 180058 t:slim X2 Insulin Pump with Interoperable Technology

X. Purpose of Special 510(k) Notification

The User Settable Max Basal Limit feature is a software update to the current t:slim X2 ACE Pump software to enhance the existing safety measures that prevent the user from setting an excessively high basal rate or temporary basal rate. This software feature allows the user to establish a limit to the basal insulin rate that can be set within the Personal Profiles, as well as the amount of insulin that can be delivered when using a temporary rate. The software feature prevents the user from setting a basal insulin rate or a temporary basal insulin rate higher than the user set Basal Limit.

The User Settable Max Basal Limit software update does not impact the automated dosing algorithms of Interoperable Automated Glycemic Controllers used with the Subject Device.

XI. 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.

XII. Device Description and Technological Characteristics

The Subject Device is identical to the predicate device- with the exception of the software updates discussed within this submission. The Subject Device is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device includes a disposable cartridge which is motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue. The desired timing and quantity of insulin delivery (bolus or basal) is programmed by the patient based on their healthcare provider's recommendations.

The Subject Device can send and receive data to and from other interoperable devices and is designed to act on commands from other authorized digital pump controller devices to adjust insulin dosing. The Subject Device is designed to be able to receive and display alerts and alarms to users based on information received from other interoperable devices. The Subject Device is compatible with Interoperable Automated Glycemic Controllers, such as Basal-IQ Technology (K193483) and Control IQ Technology (DEN190034) to aid in diabetes management. In addition, the Subject Device is compatible with iCGM systems cleared under 21 CFR 862.1355 and marketed separately from the ACE Pump and Interoperable Automated Glycemic Controllers.

	Predicate Device DEN 180058	**Subject Device**
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.	Identical
Prescription Use	Yes	Identical
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient based on health care provider recommendations.	Identical
Materials and Accessories	Alternate Controller Enabled Infusion Pump cleared under 21 CFR 880.5730	Identical
Insulin Basal Rate Delivery Range	0 units /hour- 15units/hour	Identical
Insulin Basal Rate Default	Not applicable	3 units/hour for users without established Personal Profile OR 2x (twice) the users highest programmed Basal Rate for users with an established Personal Profile
User Settable Max Basal Limit Feature	None	Yes
User Settable Max Basal Rate Range	None	0.2 units /hour- 15 units/hour
Temporary Basal Insulin Rate (Temp Rate)	A Temporary Rate set higher than 15 units/hour is capped at the pump's maximum basal rate.	A Temporary Rate cannot be set higher than the maximum rate set by the user.

XIII. Discussion of the Non-Clinical Testing

Human factors and software verification and validation tests were conducted to confirm that the User Settable Max Basal Limit software update feature 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 (R) 2013 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 verification and validation testing was carried out in accordance with ISO 14971-2012 Medical Devices - Application of Risk Management to Medical Devices, ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes and 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 level testing to ensure that the software conforms to patient needs and intended uses.

Adherence of the Special Controls listed in the Predicate Device (DEN180058), and present in the Subject Device, show continued assurance of the safety and effectiveness of the Subject Device.

XIV. Discussion of Clinical Testing

No new clinical testing was required for this Special 510(k) notification.

XV. Conclusions

The addition of the User Settable Max Basal Limit software update feature has been evaluated to be as safe and effective, and performs as well as, the Predicate Device. The addition of this software feature does not raise any new or different questions of safety or effectiveness.