November 3, 2023

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

Re: K232380
Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: August 4, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
k232380

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 in individuals 2 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 FOR K232380

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the t:slim X2 Insulin Pump with Interoperable 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	t:slim X2 Insulin Pump with Interoperable Technology
Common name	alternate controller enabled insulin infusion pump
Regulation Name	alternate controller enabled insulin infusion pump
Classification number	21 CFR 880.5730
Product code	QFG
Regulatory class	II
Predicate devices	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app (K203234)

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 in individuals 2 years of age and greater.

Description

The t:slim X2 Insulin Pump with Interoperable Technology 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 t:slim X2 insulin pump includes a disposable cartridge with a 300 unit reservoir which is filled with insulin by the user with the use of the syringe and needle. The cartridge needs to be changed every 48-72 hours depending on the type of insulin used.

The pump 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 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 t:connect mobile app enables a user to connect a smartphone to the pump using Bluetooth® wireless technology to display pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as the user's smartphone is connected to the internet.

The pump is designed to be able to receive and display alerts and alarms to users based on information received from other interoperable devices.

The pump is compatible with Interoperable Automated Glycemic Controllers, such as Basal-IQ Technology (K193483) and Control IQ Technology (K200467) to aid in diabetes management. The latter is being submitted concurrently.

In addition, the Subject Device is compatible with iCGM systems cleared under K223931 21 CFR 862.1355.

TANDEM Diabetes Care

Technological Characteristics Compared to Predicate Device

	Predicate Device T:Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Intended Use/Indication for 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.	Different: Removal of the compatible insulins NovoLog and Humalog from indications. Moved to compatible insulins section of the user guide. The Pump is indicated for use in individuals 2 years of age and greater.

	Predicate Device T:Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Technological Characteristics	The t:slim X2 insulin pump with interoperable technology 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.	Same
Classification	II	Same
Product Code	QFG	Same
Specific Drug/Biological Use	U-100 Insulin	Same
Pump Type	ACE pump, t:slim X2 system	Same
Components	Infusion Pump, Sterile disposable insulin cartridge	Same

	Predicate Device T:Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Accessories	Compatible FDA cleared infusion sets 3 mL sterile syringe and 26 gauge needle (for filling cartridge). AC power supply and DC car adaptor power supply with USB. Tandem Device Updater. Alternate USB Cable.	Similar DC car adaptor power supply is not provided with the subject device.

The t:slim X2 insulin pump with interoperable technology 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 subject device is the same as the predicate device with the following changes:

- Lowered the age indication to individuals of 2 years of age and greater.

Performance Data

Clinical testing was performed to support the expanded age indication. The clinical data demonstrates that the device shows continued assurance of safety and effectiveness.

Evaluation and adherence of the Special Controls listed in 21 CFR 880.5730 demonstrate the continued assurance of the safety and effectiveness of the device.

Substantial Equivalence

The subject device serves the same function as the predicate device with the addition of the 2–5 year-old population. The clinical testing provided in this 510(k) demonstrate that the t:slim X2 Insulin Pump with Interoperable Technology is the same as the predicate device in safety and effectiveness. Therefore, the subject device has been evaluated to be substantially equivalent to the predicate device and does not raise new or different questions of safety or effectiveness.