September 24, 2025

Tandem Diabetes Care, Inc.
Miriam Chan
Principal Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K250792
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: March 14, 2025
Received: August 26, 2025

Dear Miriam Chan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250792

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.

510(k) Summary

Company	Tandem Diabetes Care, Inc 12400 High Bluff Drive San Diego, CA 92130
Prepared	March 07, 2025
Contact	Miriam Chan Principal Regulatory Affairs Specialist mchan@tandemdiabetes.com +1(858)202-6553
Trade Name	t:slim X2 insulin pump with interoperable technology
Common Name	Alternate controller enabled infusion pump
Classification Product Code	QFG
Classification Name	Alternate controller enabled infusion pump
Regulation Number	21 CFR 880.5730
Device Class	Class II
Predicate Device	K232380, t:slim X2 insulin pump with interoperable technology

I. Device Under Review

The Subject Device, t:slim X2 insulin pump with interoperable technology ("t:slim X2 insulin pump", "the pump") is an 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 front of the pump includes a color touch screen display that has a capacitive touch panel that detects a finger touch. The Screen On Button on the side of the insulin pump is surrounded by an LED indicator light. This button is used to turn on the touch screen display so that the user can operate their System. The Screen On Button also provides users with a quick bolus option, which is a feature that allows a user to program and deliver a bolus of insulin through a sequence of presses, without using the touch screen. The System provides audio and vibratory feedback to the user to confirm the delivery. In the case of an incomplete sequence, the bolus is canceled.

The t:slim X2 insulin pump with interoperable technology system also includes: the Tandem t:slim mobile application and a 3mL (300 insulin unit) t:slim X2 cartridge and a compatible FDA cleared infusion set. The Tandem

t:slim mobile application ("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 Tandem t:slim mobile application will also be used to transmit historical pump and mobile app therapy data to the Tandem Cloud. The Tandem t:slim mobile application will be made available via the Apple® App Store for iOS compatible smartphones and the Android Play Store for Android compatible smartphones based on completed device verification and validation. The t:slim X2 cartridge is a disposable insulin cartridge compatible only with the t:slim X2 pump.

The t:slim X2 pump can be used for basal and bolus insulin delivery with or without a CGM or with any compatible interoperable automated dosing algorithm.

The pump may be used in combination with a compatible continuous glucose monitor (CGM) system. Use of CGM is optional.

II. Intended Use/ Indications 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 in individuals 2 years of age and greater.

Technological Characteristics Compared to Predicate Device K232380

	Predicate Device (K232380)	Subject Device
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,	Identical

	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.	
Prescription Use	Yes	Identical
Classification	21 CFR 880.5730	Identical
Product Code	QFG	Identical
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.	Identical
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the user based on health care provider recommendations.	Identical
Compatible Insulins	Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin	Type 1 diabetes mellitus in persons 2 years of age and greater Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin **Lyumjev U-100 Insulin**
System General Components	+ Infusion Pump + Mobile Application + Single-use, Sterile Disposable Insulin Cartridge	Identical
Cartridge Sterilization Method	Gamma Sterilization	Identical

Pump Type	ACE pump, t:slim X2 insulin pump with interoperable technology	Identical
Accessories	+ Compatible Infusion Sets + Power Supply + Belt Clip	Identical

IV. Overview of Non-Clinical and Clinical Performance Tests

Insulin compatibility and leachable testing was performed to support this 510(k) Notification. The outcome of the insulin compatibility and leachable testing demonstrates that the Subject Device is as safe and as effective as the Predicate Device.

Usability/Human Factors:

No new Usability/Human Factors testing was performed to support this 510(k) Notification.

Software Verification and Validation:

No new software testing was performed to support this 510(k) Notification.

Special Controls:

Evaluation and adherence to the Special Controls of the Predicate Device (K232380) demonstrates continued assurance of the safety and effectiveness of the Subject Device.

Conclusion:

The Subject Device has the same intended use and indications as the Predicate Device. Furthermore, the testing demonstrated that Lyumjev is a compatible insulin with t:slim X2 insulin pump with interoperable technology. The required technical documentation provided in this 510(k) demonstrates the Subject Device is as safe and as effective as the Predicate Device. 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.