July 10, 2023

Tandem Diabetes Care, Inc.
Louise Focht
Director, Regulatory Affairs
12400 High Bluff Drive
San Diego, California 92130

Re: K223213
Trade/Device Name: Tandem Mobi 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: October 14, 2022
Received: October 17, 2022

Dear Louise Focht:

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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
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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)*
k223213

Device Name
Tandem Mobi insulin pump with interoperable technology

Indications for Use *(Describe)*
The Tandem Mobi 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 six 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
K223213

Company	Tandem Diabetes Care, Inc 12400 High Bluff Drive San Diego, CA 92130
Prepared	June 9, 2023
Contact	Louise Focht Director Regulatory Affairs +1 (858) 255 6363 lfocht@tandemdiabetes.com
Trade Name	Tandem Mobi insulin pump with interoperable technology
Common Name	Ambulatory Insulin Pump
Classification Product Code	QFG
Classification Name	Alternate Controller Enabled Infusion Pump
Regulation Number	21 CFR 880.5730
Device Class	Class II
Predicate Device	K203234, t:slim X2 Insulin Pump with interoperable technology (with t:connect Mobile app)
Reference Device	K200467, Control-IQ Technology DEN180058, t:slim X2 Insulin Pump with Interoperable Technology

I. Device Under Review

The Subject Device, Tandem Mobi insulin pump with interoperable technology (" Mobi pump", "the pump"), is an Alternate Controller Enabled (ACE) Infusion Pump intended for the infusion of insulin into a patient requiring insulin therapy. The Tandem Mobi insulin pump with interoperable technology ("pump") is screenless and includes visual LED, sound and vibratory indicators to alert the user of the pump status. The Tandem Mobi insulin pump with interoperable technology system also includes: the t:connect mobile app (K203234) and a 2mL (200 insulin unit) Tandem Mobi cartridge and a compatible FDA cleared infusion set. The t:connect mobile app (" Mobile app") displays all information from, and is the primary controller of, the pump. Through the Mobile app, users will program all aspects of basal and bolus insulin delivery therapy including managing personal profiles, viewing pump and CGM data, and actively acknowledging all pump and mobile app alerts, alarms, reminders, notifications and messages. The t:connect mobile app will also be used to transmit historical pump and mobile app therapy data to the Tandem Cloud. The t:connect mobile app will be made available via the Apple® App Store for iOS compatible smartphones based on completed device verification and validation. The Tandem Mobi cartridge is a disposable insulin cartridge compatible only with the Tandem Mobi pump.

The Tandem Mobi ACE 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, such as the Dexcom G6 Continuous Glucose Monitoring System (DEN170088). Use of CGM is optional.

II. Intended Use/Indications for Use

The Tandem Mobi 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 six years of age and greater.

III. Technological Characteristics Compared to Predicate Device K203234

	Predicate Device (K203234)	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.	The Tandem Mobi 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 six years of age and greater.
Prescription Use	Prescription is required.	**SAME**
Insulin Type	NovoLog or Humalog U-100 insulin	**SAME**
Infusion Set Type	Compatible, FDA cleared infusions sets with t:lock connectors manufactured for Tandem Diabetes Care	**SAME**
Pump Type	An Alternate Controller Enabled Infusion Pump (under 21 CFR 880.5730)	**SAME**

Compatible Interoperable Devices	Compatible with: • DEN170088: Dexcom G6 Continuous Glucose Monitoring System or other compatible iCGM • K193483: Basal-IQ technology • K200467: Control-IQ technology	**SAME**
Communication with Compatible Interoperable Devices	Bluetooth Low Energy (BLE)	**SAME**
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient based on health care provider recommendations.	**SAME**
Pump Technological Characteristics	The 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.	**SAME**
Alarm Type	Visual, audible, and vibratory	**SAME**
Bolus Calculator	The Device contains a built-in bolus calculator.	**SAME**
Bolus and Basal Insulin Control	Yes	**SAME**
Display of Primary Glucose and Therapy Information	The Device can display Glucose and Therapy information and trends from the Pump and compatible interoperable devices.	**SAME** The pump does not include a graphical user interface. Instead, Primary Glucose and Therapy information and trends from the pump and compatible interoperable devices are displayed in the t:connect mobile app.
Use of t:connect Mobile app	The t:connect mobile app is optional and its use is limited to the following: • View 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. • Update historical pump data to Tandem Cloud	**SIMILAR** The t:connect mobile app is not optional. In addition to functions of the t:connect mobile app as described in the Predicate Device, the t:connect mobile app, when paired with Tandem Mobi insulin pump and running on a compatible smartphone, will be able to control all aspects of pump therapy in the same manner as the Predicate Device.

Sterilization	The pump is provided non-sterile. Cartridge provided sterile via Gamma Radiation to a Sterility Assurance Level (Sal) 10^{-6}.	**EQUIVALENT** The pump is provided non-sterile. Cartridge provided sterile via Ethylene Oxide Gas to a Sterility Assurance Level (Sal) 10^{-6}.
Cartridge Length of Use	Every 2 or 3 days depending on insulin type used	**SIMILAR** Every 3 days for compatible insulins

IV. Overview of Non-Clinical Performance Tests

Appropriate testing was performed to confirm the Subject Device met specified requirements and performed as intended. See summaries below.

Usability/Human Factors:

Human Factors validation testing was conducted to demonstrate intended users can effectively use the Subject Device for its intended purpose in its expected use environment.

Usability tasks were evaluated in accordance with ANSI AAMI HE 75 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 Validation study demonstrate users can safely and effectively use the features of the Subject Device in expected use environment.

Software Verification and Validation:

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 user needs and intended use. 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 with Content of Premarket Submissions for Management of Cybersecurity in Medical Devices- Guidance for Industry and Food and Drug Administration Staff.

The Subject Device software was verified and validated to meet acceptance criteria and

performed as intended.

Electrical Safety/ EMC:
Electrical and Electromagnetic Compatibility (EMC) Testing were performed according to applicable requirements set forth in IEC 60601 general standard. Results confirm the Subject Device met specified requirements.

Insulin Compatibility and Biocompatibility:
The Subject Device utilizes the same insulin as the Predicate Device. Insulin Compatibility Testing was performed to ensure the indicated insulin performed as intended in the Subject Device. In addition, biocompatibility of the Tandem Mobi sleeve accessory was performed and met the acceptance criteria. Results confirm the Subject Device met specified requirements.

Sterilization and Shipping:
Sterilization, packaging, storage and shipping testing was conducted to ensure the Subject device met the requirements. Results confirm the sterilization and shipping integrity of the system.

Special Controls:
Evaluation and adherence to the Special Controls of the Predicate Device (K203224) and Reference Devices (K200467 and DEN180085) demonstrate continued assurance of the safety and effectiveness of the Subject Device.

Clinical Testing:
No new clinical testing was performed to support this Traditional 510(k) Notification.

Conclusion:
The Subject Device serves the same function as the Predicate Device. Furthermore, the Subject Device performs insulin therapy functions that are the same as that of the Predicate Device. The required technical documentation provided in this Traditional 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.