November 6, 2025

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

Re: K253074
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: September 22, 2025
Received: September 23, 2025

Dear Omar Mirza:

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253074

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 2 years of age and greater.

Control-IQ+ technology is intended for use with compatible interoperable continuous glucose monitors (iCGM), alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ+ technology is not a substitute for your own active diabetes management. Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater. Control-IQ+ technology is intended for single patient use and requires a prescription

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Company	Tandem Diabetes Care, Inc 12400 High Bluff Drive San Diego, CA 92130
Prepared	22 Sept 2025
Contact	Omar Mirza Sr. Regulatory Affairs Specialist +1 (954) 6082297 omirza@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	K241078, Tandem Mobi 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 Tandem Mobi mobile application and a 2mL (200 insulin unit) Tandem Mobi cartridge and a compatible FDA cleared infusion set. The Tandem Mobi mobile application ("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 Tandem Mobi mobile application will also be used to transmit historical pump and mobile app therapy data to the Tandem Cloud. The Tandem Mobi mobile application will be made available via the Android Play® App store for Android-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. 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 2 years of age and greater.

III. Technological Characteristics Compared to Predicate Device K241078

	Predicate Device K241078	**Subject Device**
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 2 years of age and greater.	**SAME**
Prescription Use	Prescription is required.	**SAME**
Insulin Type	NovoLog U-100 insulin Humalog U-100 insulin	**SAME**

	Predicate Device K241078	Subject Device
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 (21 CFR 880.5730)	**SAME**
Compatible Interoperable Devices	Compatible with: • DEN170088: Dexcom G6 Continuous Glucose Monitoring System or other compatible iCGM • K200467: Control-IQ technology	Compatible with: • K213919: Dexcom G7 Continuous Glucose Monitoring System or other compatible iCGM • K250798: Control-IQ+ technology
Communication with Compatible Interoperable Devices	Bluetooth Low Energy (BLE)	**SAME**
Principles of Operation	Delivery of Insulin (Bolus and Basal) programmed by 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**

	Predicate Device K241078	**Subject Device**
	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 Tandem Mobi mobile application.	
Mobi Mobile App Availability	The Tandem Mobi mobile app is currently available via the Apple® App Store® for iOS compatible smartphones.	The Tandem Mobi mobile app will be made available via the Google® Play store for Android compatible smartphones.
Mobile App Functionalities	The Mobi mobile app (iOS) has the following functionalities: • View Pump therapy data, trends, alerts, alarms, notifications, and reminders. • 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 Tandem Mobi insulin pump or the Tandem Mobi mobile app. • Display history logs • Update historical pump data to Tandem Cloud • Mobile Tandem Device Updater (mTDU)	Subject device has the same functionalities mentioned in the predicate device. Some minor differences include: • Native Android User Interface Controls: Standard Android UI components • Location Permission requirement for Bluetooth® pairing • Update historical pump data to Tandem Source Cloud • History logs will not be displayed on the Mobi Android mobile application. The historical pump data will continue to be uploaded to the Tandem Source Cloud, which allows users to view the historical pump data

	Predicate Device K241078	Subject Device
		on Tandem Source
Remote software updates	**<u>Pump</u>** Remote software updates available via Mobile Tandem Device Updater (mTDU) via Bluetooth Low Energy (BLE) Radio on the Mobi Pump to review remote software updates. mTDU is not a medical device. **<u>Mobile App</u>** Updated via the Apple® App Store®.	**<u>Pump</u>** SAME **<u>Mobile App</u>** Updated via the Google® Play App store.
Sterilization	The pump is provided non-sterile. The cartridge is provided sterile via E-Beam (Irradiation) to a Sterility Assurance Level ,SAL 10^{-6}.	**SAME**
Cartridge Length of Use	Every 3 days for compatible insulins.	**SAME**

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.

<u>Usability/Human Factors:</u>

The Tandem Mobi system was previously validated for usability with the cleared predicate device. For this 510(k) Notification, no new human factors validation testing was required because the Android mobile application represents a platform translation of the existing iOS app. While platform-specific functional differences exist, no new user-facing features, workflows, or critical tasks were introduced.

A comparative use-related risk analysis was performed to evaluate the impact of translating the user interface to the Android operating system. This analysis confirmed that no new critical tasks were introduced, and no existing critical tasks were impacted. Formative testing and human factors validation were therefore not repeated. The intended users, use environments, and user interface specifications remain consistent with the predicate system, and the Android mobile application can be safely and effectively used as intended.

Software Verification and Validation:

The Android version of the Tandem Mobi mobile application was developed under Tandem's quality system in compliance with IEC 62304 and IEC 82304. The software lifecycle included documented requirements, design, risk management, and traceability through verification and validation. Verification activities included unit testing, code reviews, static analysis, and system integration testing. Validation confirmed end-to-end functionality of the Android version of the Tandem Mobi mobile application with the Mobi pump, a compatible continuous glucose monitor, and the Tandem Source cloud. Testing was performed independently from development to ensure objectivity. All acceptance criteria were met, demonstrating that the software performs as intended and introduces no new hazards relative to the predicate device.

Electrical Safety/ EMC:

Electrical safety testing in accordance with IEC 60601-1 requirements was previously completed at the system level for the Tandem Mobi pump hardware. The Android mobile application does not alter the pump's hardware design, electrical energy transfer, or safety-related functions; therefore, the previous results remain applicable to this submission. For the current submission, testing related to electromagnetic compatibility (EMC) and wireless function were conducted to evaluate the Tandem Mobi Pump System with the Android mobile application.

To qualify the Android mobile application, reduced-scope testing was successfully performed to satisfy IEC 61000-4-3:2020 and IEC 61000-4-39:2017 per (IEC 60601-1-2:2014/A1:2020 (Ed. 4.1)), ANSI C63.27-2021, and RTCA DO-160G (2010) testing requirements to evaluate electromagnetic immunity, wireless coexistence, bluetooth range, and household emitter interference. Testing confirmed acceptable pump-to-app and pump-to-CGM communication under conditions presented by the test standards and test protocols.

Results demonstrated that the limited-scope Android testing was consistent with the prior iOS full-scope testing and did not introduce EMC risks. Collectively, the combined body of evidence confirms the Tandem Mobi system maintains safe and effective performance under electromagnetic stress and wireless coexistence conditions, supporting substantial equivalence to the cleared predicate device.

Insulin Compatibility and Biocompatibility:

No new insulin compatibility or biocompatibility testing was required for this 510(k) Notification. The Tandem Mobi cartridge, infusion sets, and patient-contacting materials remain unchanged from the predicate device.

Sterilization and Shipping:

No changes were made to sterilization methods or packaging integrity as part of this 510(k) Notification. The disposable Tandem Mobi insulin cartridge continues to be terminally sterilized using e-beam irradiation and validated per ISO 11137.

Special Controls:

Evaluation and adherence to the Special Controls of the Predicate Device (K241078) demonstrates continued assurance of the safety and effectiveness of the Subject Device.

Clinical Testing:

No new clinical testing was provided to support this 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 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.