



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K253074

B Applicant

Tandem Diabetes Care, Inc.

C Proprietary and Established Names

Tandem Mobi insulin pump with interoperable technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	II	880.5730 – Alternate controller enabled infusion pump	CH - Clinical Chemistry

A Purpose for Submission:

Modification to the device to add a new mobile application which is compatible with Android devices.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Tandem Mobi insulin pump is not intended for anyone unable or unwilling to:

- Use the pump, CGM, and all other system components in accordance with their respective instructions for use.
- Test blood glucose (BG) levels as recommended by their healthcare provider.
- Maintain sufficient diabetes self-care skills.
- See their healthcare team regularly.
- Demonstrate adequate carbohydrate-counting skills.

The user must also have adequate vision and/or hearing in order to recognize all functions of the pump, including alerts, alarms, and reminders.

Some skin care products such as lotions, sunscreens, and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. DO NOT allow these products to come in contact with the pump or cartridge. ALWAYS remove your pump before applying these products and ALWAYS wash your hands before handling your pump or cartridge after using such products. ALWAYS change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

The Tandem Mobi insulin pump with interoperable technology and the Tandem Mobi Cartridge are compatible with the following U-100 insulins: Humalog and Novolog.

III Device Description

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 pump may be used in combination with a compatible integrated continuous glucose monitor (iCGM) system or with compatible interoperable automated glycemic controllers (iAGC). Use of iCGM and iAGC is optional.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Tandem Mobi Insulin Pump with interoperable technology

B Predicate 510(k) Number(s):

K241078

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K253074</u>	<u>K241078 (predicate)</u>
Device Trade Name	Tandem Mobi Insulin Pump with interoperable technology	Tandem Mobi Insulin Pump with interoperable technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. Intended to be interoperable with connected devices including CGMs and automated insulin dosing algorithms.	Same
Insulin Type	NovoLog or Humalog U-100 insulin	Same
Communication with Compatible Interoperable Devices	Bluetooth Low Energy (BLE)	Same
General Device Characteristic Differences		
Mobi Mobile App OS Compatibility	iOS and Android	iOS

V Standards/Guidance Documents Referenced:

ANSI AAMI ISO 14971: 2019: Medical devices – Applications of risk management to medical devices Complete FDA recognition 5-125

ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements Complete FDA recognition 5-134

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Complete FDA recognition 19-49

ISO 20417 First edition 2021-04 (Corrected version 2021-12): Medical devices - Information to be supplied by the manufacturer Complete FDA recognition 5-135

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION: Medical devices–Part 1: Application of usability engineering to medical devices. Complete FDA recognition 5-129

ANSI AAMI HE75:2009/(R)2018: Human Factors engineering – Design of Medical Devices Partial FDA recognition 5-57

AAMI IEC 62304:2006/A1:2016: Medical Device Software – Software Lifecycle Processes Complete FDA recognition 13-79

AAMI TIR 45:2012: Guidance on the use of AGILE practices in the development of medical device software Complete FDA recognition 13-36

VI Performance Characteristics:

A. Analytical Performance

The analytical performance of the Tandem Mobi Pump was previously established and described in the public decision summary for K223213.

B. Other Supportive Instrument Performance Characteristics Data

Usability/Human Factors:

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:

Conducted per IEC 62304:2006/A1:2015, including code reviews, static analysis, unit testing, system-level verification, and validation. Graphical user interface verification confirmed correct Android-specific display and navigation, with performance equivalent to the cleared iOS version.

Electrical Safety/ EMC:

Tandem performed testing to demonstrate compliance with basic safety and essential

performance in accordance with 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). The device complies with those standards.

Wireless Coexistence:

Evaluated per ANSI/IEEE C63.27-2021, as well as range and household coexistence protocols. Reports demonstrated robust BLE communication in coexistence, range, and household environments with no loss of safety or performance.

Cybersecurity:

Conducted per FDA's 2025 Cybersecurity Guidance and §524B of the FD&C Act. Included SAST, internal security testing, and third-party penetration testing aligned with OWASP MASVS. Results showed no critical unresolved vulnerabilities and confirmed confidentiality, integrity, and availability objectives. Detailed information on cybersecurity of the device was reviewed and found to be acceptable.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.