510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K240309

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	Class II	21 CFR 880.5730 – Alternate Controller Enabled Infusion Pump	CH - Clinical Chemistry

E Purpose for Submission:

Modification to a cleared device to expand the age indication (from ≥ 6 years old to ≥ 2 years old), and to add a new mobile app unique to the Mobi pump.

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 two 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.

The pump is magnetic resonance (MR) unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room.

Do not expose your pump, transmitter, or sensor to X-ray, CT, MRI, PET, or other exposure to radiation.

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 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 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):

K233044

C Comparison with Predicate(s):

Device & Predicate Device(s):	K240309	K233044 (predicate)
Device Trade Name	Tandem Mobi Insulin Pump with interoperable technology	Tandem Mobi Insulin Pump with interoperable technology
General Device Characteristic Similarities		
Intended 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	Same

	dosing algorithms.	
Insulin Type	NovoLog or Humalog U-100 insulin	Same
Communication with Compatible Interoperable Devices	Bluetooth Low Energy (BLE)	Same
General Device Characteristic Differences		
Intended Population	Individuals two years of age and greater	Individuals six years of age and greater
Primary Controller	Tandem Mobi Mobile Application	t:connect Mobile App

V Standards/Guidance Documents Referenced:

ISO 14971 Third Edition 2019-12: Medical Devices - Application of risk management to medical devices FDA Recognition no: 5-125

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION: Medical device software – Software life cycle processes FDA Recognition no: 13-79

VI Performance Characteristics:

A Analytical Performance:

Bench testing data is leveraged from K223213.

B Other Supportive Instrument Performance Characteristics Data:

Human Factors:
A comparative Use Related Risk Analysis was performed to support leveraging human factors validation testing from K223213.

Software Verification and Validation
Detailed information on software of the device was reviewed and found acceptable.

Cybersecurity:
Tandem has provided cybersecurity risk management documentation based on the National Institute of Standards and Technology, medical Device Privacy Consortium, FDA guidelines, and the Open Web Application Security Project. Cybersecurity documentation includes assessment of the threat model, vulnerabilities, SBOM, and penetration testing. The cybersecurity 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.