510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K241078

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 change the sterilization method from ethylene oxide sterilization to electron beam sterilization.

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):

K240309

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241078	K240309 (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		
Sterilization	The pump is provided non-sterile. The cartridge is provided sterile via Irradiation to a Sterility Assurance Level (SAL) 10^{-6}.	The pump is provided non-sterile. The cartridge is provided sterile via Ethylene Oxide Gas to a Sterility Assurance Level (SAL) 10^{-6}.

V Standards/Guidance Documents Referenced:

ISO 14971 Third Edition 2019-12: Medical Devices – Application of Risk Management to Medical Devices. Complete FDA recognition 5-125.

ISO 10993-1 Fifth Edition 2018-08. Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. Partial FDA recognition 2-258.

ISO 10993-3 Third Edition 2014-10-1: Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity. Partial FDA Recognition 2-228.

ISO 10993-5 Third Edition 2009-06-01: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity. Complete FDA Recognition 2-245.

ISO 10993-10 Fourth edition 2021-11: Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization. Partial FDA Recognition 2-296.

ISO 10993-11 Third Edition 2017-09: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. Complete FDA Recognition 2-255].

ISO 10993-12 Fifth edition 2021-01: Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. Complete FDA Recognition 2-289.

ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05 AMD1 2022-05: Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process. Partial FDA Recognition 2-298.

ISO/TS 10993-19 Second edition: Biological Evaluation of Medical Devices – Part 19: Physico-chemical, Morphological and Topographical Characterization of Materials. Complete FDA Recognition 2-281.

ISO 10993-23 First Edition 2021-01: Biological Evaluation of Medical Devices – Part 23: Tests for Irritation. Partial FDA Recognition 2-291.

ISO 11137-1: Third Edition 2006-04-15: "Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices [Including Amendment 1 (2013) and Amendment 2 (2018)]." Complete FDA Recognition 14-528.

ISO 11137-2: Third Edition 2013-06 [Including AMD1:2022: "Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose [Including Amendment 1 (2022)]." Complete FDA Recognition 14-580.

VI Performance Characteristics:

A Analytical Performance:

Bench testing data is leveraged from K223213.

B Other Supportive Instrument Performance Characteristics Data:

The following non-clinical tests related to the design changes of the Mobi cartridge were conducted: Drug Compatibility, Biocompatibility, Sterilization Validation, Package Testing, Pump infusion delivery hazard detection and accuracy, and Mobi cartridge mechanical design testing

Drug Compatibility
Drug compatibility testing for U-100 NovoLog and U-100 Humalog was performed for the updated Tandem Mobi cartridge with updated materials and sterilization changes. Study results included in this 510(k) submission were found to be acceptable.

Biocompatibility
Biocompatibility testing was performed per ISO 10993-1:2018, FDA Guidance Document: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and FDA special controls for alternate controller enabled infusion pumps for the updated cartridge. All endpoints were tested adequately, and results were acceptable.

Sterilization Validation
The Tandem Mobi Cartridge and components used to fill the cartridge are provided sterile. The cartridge is terminally sterilized in its final package using Irradiation and the process has been validated to assure a Sterility Assurance Level (SAL) of 10^{-6} using the VDmax25 method in accordance with ISO 11137-2: Third Edition 2013-06 [Including AMD1:2022]: "Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose [Including Amendment 1 (2022)]." The test results were found to be acceptable.

Package Testing
The Tandem Mobi cartridge 10 pack and 2 pack packaging and sterile barrier were tested and the results were found to be acceptable.

Pump Infusion Delivery Hazard Detection and Accuracy
Pump delivery hazard detection and accuracy requirements related to design changes included in this submission were tested and found to be acceptable.

Mobi Cartridge Mechanical Design Testing
Mobi cartridge mechanical design requirements related to design changes included in this submission were tested 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.