510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K223213

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 Pump	CH - Clinical Chemistry

E Purpose for Submission:

New device

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 six years of age and greater.

C Special Conditions for Use Statement(s):

This device is for prescription use only.

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

- Use the pump, and other system components in accordance with their respective instructions for use.
- Test blood glucose (BG) levels as recommended by their healthcare team.
- Maintain sufficient diabetes self- care skills.
- See their healthcare team regularly.
- Demonstrate adequate carbohydrate-counting skills (preferred, not required).

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

The device must be removed before Magnetic Resonance Imaging (MRI).

Exposure of the pump to X-ray, Computed Tomography (CT) scan, MRI, Positron Emission Topography (PET) can damage the pump.

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 Tandem Mobi insulin pump with interoperable technology is an Alternate Controller Enabled (ACE) Infusion Pump intended for the infusion of insulin into a patient requiring insulin therapy. It is screenless and includes visual LED, sound and vibratory indicators to alert the user of the Pump status. The pump also includes: the t:connect mobile app and a 2mL (200 insulin unit) Mobi™ Cartridge and a compatible FDA cleared infusion set. The t:connect mobile app displays all information from, and is the primary controller for the pump.

The pump includes a disposable cartridge which is a motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissues.

The pump is designed to be used by a single person and has a useful life of 4 years. The disposable cartridge should be changed every 3 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

t:slim X2 Insulin Pump with interoperable technology (with t:connect Mobile app)

B Predicate 510(k) Number(s):

K203234

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223213	K203234
Device Trade Name	Tandem Mobi insulin pump with interoperable technology	t:slim X2 insulin pump with interoperable technology (with t:connect Mobile app)
General Device Characteristic Similarities		
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.	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.
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 Insulin. Humalog or Novolog	Same

Insulin Delivery Modes	Both basal and bolus	Same
Insulin Basal Rate Delivery Range	0 – 15 U/hour	Same
Insulin Bolus Delivery Range	0.01 U at volumes greater than 0.05 U, Max bolus volume 25 U	Same

V Standards/Guidance Documents Referenced:

- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016
- FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" dated October, 2018
- FDA Guidance "General Principles of Software Validation" dated January, 2002
- ISO 10993-1:2018 Biological Evaluation of Medical Devices: Evaluation and Testing
- ISO 10993-3:2014 Biological Evaluation of Medical Devices: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO 14971: 2019 +A11:2021 Medical Devices – Application of Risk Management to Medical Devices
- IEC 60601-1:2005+AMD 1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances-Requirements and Tests
- IEC 60601-1-6:2010 + AMD 1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8:2006 + AMD 1:2012 Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- IEC 60601-1-11 Issued: 2015/01/20 Ed.2 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard-Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- IEC 62366-1: 2005 Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices

- ISO 11607-1:2020 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [including Amendment 1 (2014)
- ISO 11135: 2014 Sterilization of health care products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices.

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum basal rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new and 16 had been aged to simulate at least four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of aging. Delivery accuracy was assessed by pumping insulin into a container on a scale and measuring the weight of the liquid at 1h, 6h, and 12h intervals for minimum, intermediate rates and maximum basal rates of 0.1, 2.0 U/hr and 15 U/hr, respectively. For the minimum basal rate, accuracy is reported after a 1-hour warm-up period.

The following tables report the typical basal performance (average) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum basal rate settings for all pumps tested.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 0.1 U/hr (minimum) basal rate setting

0.1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.1 U**	**0.6 U**	**1.2 U**
Median amount delivered [min, max]	0.09 U [0.07, 0.18]	0.60 U [0.37, 0.73]	1.21 U [0.84, 1.38]

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 2.0 U/hr (medium) basal rate setting

2.0 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**2.0 U**	**12.0 U**	**24.0 U**
Median amount delivered [min, max]	1.9 U [1.5, 2.1]	12.1 U [10.7, 12.5]	24.4 U [21.8, 25.0]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 15.0 U/hr (high) basal rate setting

15.0 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**15.0 U**	**90.0 U**	**180.0 U**
Median amount delivered [min, max]	15.3 U [12.3, 15.6]	90.5 U [84.4, 91.0]	180.0 U [174.2, 181.4]

2. Bolus delivery accuracy

To assess bolus delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.05, 2.5, and 25 U). Sixteen of the pumps were new and 16 had been aged to simulate five years of regular use. For both aged and unaged pumps, eight pumps were tested with an unaged cartridge, and eight with a cartridge which underwent one year of accelerated aging.

Tables 4-6 below show the number (and %) of boluses within the specified range of each target bolus volume.

Table 4: Amount of fluid delivered after a 0.05 U bolus request (n=800 boluses)

Units delivered after a 0.05 U bolus request (% of commanded units)										
	<0.0125 (<25 %)	0.0125 - 0.0375 (25-75 %)	0.0375-0.045 (75-90 %)	0.045-0.0475 (90-95 %)	0.0475-0.0525 (95-105 %)	0.0525-0.0550 (105-110 %)	0.055-0.0625 (110-125 %)	0.0625-0.0875 (125-175 %)	0.0875-0.125 (175-250 %)	>0.125 (>250 %)
Number and percent of boluses	0/800 (0.0 %)	2/800 (1 %)	17/800 (2 %)	42/800 (5 %)	495/800 (62 %)	185/800 (23 %)	59/800 (7 %)	0/800 (0 %)	0/800 (0 %)	0/800 (0 %)

Table 5: Amount of fluid delivered after a 2.5 U bolus request (n=800 boluses)

Units delivered after a 2.5 U bolus request (% of commanded units)										
	<0.625 (<25 %)	0.625-1.875 (25-75 %)	1.875-2.25 (75-90 %)	2.25-2.375 (90-95 %)	2.375-2.625 (95-105 %)	2.625-2.75 (105-110 %)	2.75-3.125 (110-125 %)	3.125-4.375 (125-175 %)	4.375-6.25 (175-250 %)	>6.25 (>250 %)
Number and percent of boluses	0/800 (0 %)	0/800 (0 %)	2/800 (0 %)	19/800 (3 %)	736/800 (92 %)	43/800 (6 %)	0/800 (0 %)	0/800 (0 %)	0/800 (0 %)	0/800 (0 %)

Table 6: Amount of fluid delivered after a 25 U bolus request (n=192 boluses)

Units delivered after a 25 U bolus request (% of commanded units)										
	<6.25 (<25 %)	6.25-18.75 (25-75 %)	18.75-22.5 (75-90 %)	22.5-23.75 (90-95 %)	23.75-26.25 (95-105 %)	26.25-27.5 (105-110 %)	27.5-31.25 (110-125 %)	31.25-43.75 (125-175 %)	43.75-62.5 (175-250 %)	>62.5 (>250 %)
Number and percent of boluses	0/192 (0 %)	0/192 (0 %)	0/192 (0 %)	0/192 (0 %)	192/192 (100 %)	0/192 (0 %)	0/192 (0 %)	0/192 (0 %)	0/192 (0 %)	0/192 (0 %)

3. Occlusion detection

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 32 pumps that were also used for bolus and basal accuracy were used here. The occlusion tests were performed with bolus sizes of 2.5 U and 25 U and basal rates of 0.1 and 2 U/hr and typical and maximum time to occlusion detection are shown below in Table 7.

Table 7: Timing of occlusion detection alarms

	Typical time to occlusion detection	**Maximum time to occlusion detection**
≥ 2.5 U Bolus	46 seconds	3 minutes
2 U/hr Basal	40 minutes	2 hours
0.1 U/hr Basal	17 hours 11 minutes	36 hours

B. Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

A comprehensive hazard analysis was reviewed, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed. The sponsor performed a hazard analysis to account for the unique intended use, design elements, and risks of their ACE pump. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors validation tests were conducted with the Tandem Mobi pump. All study participants received training that was consistent with the training that patients would receive with the commercial product. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the ACE Pump is validated for its intended use.

3. 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 disposable cassette, pump and the disposable cassette packaging and dust cover. All endpoints were tested adequately, and results were acceptable.

4. Sterility

The Tandem Mobi cartridge and components used to fill the cartridge are provided sterile. The cartridge is terminally sterilized in its final package using Ethylene Oxide and the process has been validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11135: 2014. In addition, testing performed per ISO 10993-7:2008+A1:2019 and ISO 11135:2014 was found acceptable.

5. Insulin Compatibility and Stability

The Tandem Mobi pump cartridge is compatible with U-100 insulins Novolog (insulin aspart) and Humalog (insulin lispro) for up to 3 days.

6. Additional Bench Testing

In addition to the performance testing described above, mechanical testing, simulated use testing, and other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified. Summaries for reliability, safety, and verification testing follow:

Testing to Support System Reliability
Durability of pumping mechanism
Bolus Button
Pump Alarm
Pump and cartridge mating
Pump Battery
Remote Interface including screen, volume button, vibration interface, battery
Vibration and shock
Chemical stressors (e.g. insect repellents, lotions)

Testing to Support System Safety
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Design specific tests: Volume Cross Checks, Inter and Intra Delivery Leaks
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing
Incidental Delivery
Worst Case Accuracy

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Infusion pressure Testing
Alarms Testing
Data Handling Testing
Pump Activation Testing
Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing
Environmental conditions Testing

7. Electromagnetic Compatibility and Wireless Coexistence

Electromagnetic compatibility (EMC), electromagnetic immunity (EMI) and wireless coexistence testing was performed for the pump in compliance with IEC 60601-1- 2 and RTCA DO-160G. The device passed all required testing with appropriate acceptance criteria and no deviations. Radiofrequency wireless testing was conducted, including wireless coexistence. Testing demonstrated that the device can operate in the presence of RF interference and co-exists with other wireless devices operating in the same vicinity. All tests passed.

8. Basic Safety and Essential Performance (Electrical Safety)

The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalence for this device.

9. Data Logging

The sponsor provided a summary of pump and controller logging capability which enable the device to record critical events including insulin delivery, pump commands and confirmations, connectivity states, malfunctions, and alarms. These were reviewed and found to be adequate.

10. Interoperability

A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

11. Software and Cybersecurity

Detailed information on software and cybersecurity of the device was reviewed and found 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.