510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K250792

B Applicant

Tandem Diabetes Care, Inc.

C Proprietary and Established Names

t:slim X2 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:

The purpose of this submission is to add Lyumjev U-100 insulin as a compatible insulin to the labeling of the subject device.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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 in individuals 2 years of age and greater.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

You must take off your pump and leave it outside the procedure room if you are going to have any of the following medical procedures: magnetic resonance imaging (MRI), x-ray, computed tomography (CT) scan, positron emission tomography (PET) scan, other exposure to radiation, pacemaker/automatic implantable cardioverter defibrillator (AICD) placement or reprogramming, cardiac catheterization, or nuclear stress test. Always notify the provider/technician about your diabetes and your pump. If you need to discontinue use of the pump for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your BG before disconnecting from the pump and again when you reconnect and treat high BG levels as recommended by your healthcare provider.

Always ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the Tandem t:slim mobile app. Confirm that the information displayed to you matches your signs and symptoms. If the information displayed to you in your Tandem t:slim mobile app does not match your signs and symptoms, always refer to the t:slim X2 insulin pump before making any treatment decisions.

For patients who do not self-manage their disease, the Security PIN function should always be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events.

For patients whose insulin administration is managed by a caregiver, always turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled.

III Device Description

The t:slim X2 Insulin Pump with Interoperable Technology 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 front of the pump includes a color touch screen display that has a capacitive touch panel that detects a finger touch. The Screen On Button on the side of the insulin pump is surrounded by an LED indicator light. This button is used to turn on the touch screen display so that the user can operate their System. The Screen On Button also provides users with a quick bolus option, which is a feature that allows a user to program and deliver a bolus of insulin through a sequence of presses, without using the touch screen. The System provides audio and vibratory feedback to the user to confirm the delivery. In the case of an incomplete sequence, the bolus is canceled.

The t:slim X2 insulin pump with interoperable technology system also includes: the Tandem t:slim mobile application and a 3 mL (300 insulin unit) t:slim X2 cartridge and a compatible FDA cleared infusion set. The Tandem t:slim mobile application ("mobile app") enables a user to connect a smartphone to the pump using Bluetooth® wireless technology to display pump information and perform some pump functions on the smartphone as well as display pump notifications. The Tandem t:slim mobile application can also be used to transmit historical pump and mobile app therapy data to the Tandem Cloud. The t:slim X2 cartridge is a disposable insulin cartridge compatible only with the t:slim X2 pump.

The pump may be used in combination with a compatible continuous glucose monitor (CGM) system. The t:slim X2 pump can be used for basal and bolus insulin delivery with or without a CGM or with a compatible interoperable automated glycemic controller, such as the Basal-IQ Technology or the Control IQ Technology to aid in diabetes management.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

t:slim X2 Insulin Pump with Interoperable Technology

B Predicate 510(k) Number(s):

K232380

C Comparison with Predicate(s):

Device & Predicate Device(s):	K250792	K232380
Device Trade Name	t:slim X2 insulin pump with interoperable technology	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	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	Same

	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.	
General Device Characteristic Differences		
Compatible Insulins	For Type 1 diabetes mellitus in persons 2 years of age and greater and Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin Lyumjev U-100 Insulin	For Type 1 diabetes mellitus in persons 2 years of age and greater and Type 2 diabetes mellitus in persons 18 years of age and greater: NovoLog U-100 Insulin Humalog U-100 Insulin

V Standards/Guidance Documents Referenced:

- ANSI AAMI ISO 14971:2019 – "Medical devices - Applications of risk management to medical devices"

VI Performance Characteristics:

A. Analytical Performance

The accuracy in basal delivery, bolus delivery and occlusion detection remain unchanged from the predicate.

B. Other Supportive Instrument Performance Characteristics Data

The sponsor conducted in vitro insulin compatibility testing with Lyumjev U-100 insulin to verify that the pumps and the insulin are compatible. The stability of the insulin product was evaluated under stressed, worst-case conditions. The studies observed acceptable results and support the compatibility of this insulin product with these pumps.

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.