510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K232380

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:

Modification to a cleared device to expand the age indication (from ≥ 6 years old to ≥ 2 years old).

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

Remove the t:slim X2 Insulin Pump before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The magnetic fields and heat could damage the components of the t:slim X2 insulin pump with interoperable technology. Please review your smart phone manufacturer's instructions before using the t:connect mobile app during any of the procedures listed.

Always ensure the pump has a healthy Bluetooth wireless technology connection with your t:connect mobile app before you use the t:connect mobile app to make treatment decisions. Confirm that the information displayed to you matches your signs and symptoms. If necessary, make sure that your pump and phone are connected and the information displayed matches when making 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.

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 pump consists of an user-operated interface display, an electronic microprocessor software control system including Bluetooth radio and signal processing algorithms that allows the pump to receive continuous glucose monitoring data from an integrated continuous glucose monitoring system. Based on this data, and the thresholds set by users in consultation with healthcare providers, the pump can identify high or low glucose levels, as well as rapidly rising or falling glucose conditions.

The pump also houses an audible speaker and vibrator to provide alarms, alerts and reminders to the user. The insulin cartridge is designed to hold up to 3 mL, or 300 Unites of U-100 insulin. The insulin cartridge is intended to be replaced at least once every three days.

The t:slim X2 system is compatible with interoperable Automated glycemic controllers, such as the Basal-IQ Technology and 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):

K203234

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232380	K203234
Device Trade Name	t:slim X2 Insulin Pump with Interoperable Technology	Same
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 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.	Same
General Device Characteristic Differences		
Intended User Population	2 years and older with Type 1 diabetes mellitus.	6 years and older with Type 1 diabetes mellitus.

V Standards/Guidance Documents Referenced:

Not applicable.

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

a) Software: Sponsor made minor changes to the software including modifications to the user interface. Software documentation was reviewed and found to be adequate.

b) Human Factors: Sponsor leveraged human factors studies previously performed under K203234 for the six years and older age group for their current submission with adequate justification.

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.