



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY**

**I Background Information:**

**A 510(k) Number**

K203234

**B Applicant**

Tandem Diabetes Care, Inc.

**C Proprietary and Established Names**

t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)

**D Regulatory Information**

<b>Product Code(s)</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump	CH-Clinical Chemistry

**II Submission/Device Overview:**

**A Purpose for Submission:**

Modification of the cleared t:slim X2 Insulin Pump with interoperable technology to add the t:connect mobile app to request insulin boluses, receive alerts and alarms, and view pump data.

**B Type of Test:**

Not applicable.

**III 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 with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 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.

**IV Device/System Characteristics:****A Device Description:**

The t:connect mobile app provides t:slim X2 insulin pump users an optional method of viewing therapy data and partially controlling aspects of their current insulin pump via Android or iOS smart devices. The app is compatible with the cleared t:slim X2 Insulin Pump with Interoperable Technology, which includes an integrated user interface providing functionality such as visualization of glucose values derived from a compatible iCGM (interoperable continuous glucose monitor) as well as the ability to partially control therapeutic delivery of insulin.

Once successfully downloaded, pairing of devices begins with a unique code generated and used by the user to ensure secure Bluetooth communications between the smartphone and the Pump. The t:connect mobile app will allow wireless communication between the user's

personal pump and personal Android or iOS device. The t:connect mobile app graphical user interface (GUI), while not identical, includes features of the Pump GUI in form and function.

This optional app-based controller can be utilized by the end user for the purposes of remotely:

- Viewing therapy data and trends displayed on the Pump user interface
- Viewing real-time glucose values and trends
- Programming insulin boluses using bolus calculator to remotely request a bolus delivery as well as cancelling or stopping a requested insulin bolus from being delivered (*regardless of bolus request being made on the Pump or the app*)
- Viewing alerts and alarms received from the Pump as Push notifications

The app displays glucose information derived from the Dexcom G6 System but *does not* permit a user to enable automated insulin delivery remotely or program and deliver extended boluses or basal insulin.

The t:connect mobile app is not a replacement for the information displayed on the Pump, therefore users can still view pump therapy data/trends, program requests, and cancel or stop boluses from their Pump without the t:connect mobile app.

## **B Instrument Description Information:**

1. Instrument Name:

t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)

2. Specimen Identification:

Not applicable.

3. Specimen Sampling and Handling:

Not applicable.

4. Calibration:

Not applicable.

5. Quality Control:

Not applicable.

## **V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

t:slim X2 Insulin Pump with Interoperable Technology

**B Predicate 510(k) Number(s):**

K201214

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K203234</u>	<u>K201214</u>
Device Trade Name	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)	t:slim X2 Insulin Pump with Interoperable Technology
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications for Use	<p>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.</p> <p>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.</p>	Same

General Device Characteristic Differences		
User Interface (UI)	Touchscreen on the pump or a compatible smartphone running the t:connect mobile app.	Touchscreen on the Pump

**VI Standards/Guidance Documents Referenced:**

- ANSI/AAMI/EN ISO 14971:2007(R)2010 Medical Devices - Application of Risk Management to Medical Devices (FDA Recognition Number 5-40)
- ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)] (FDA Recognition Number 13-79)
- ANSI AAMI HE 75:2009 Human Factors Engineering-Design of Medical Devices (FDA Recognition Number 5-57)
- ANSI/AAMI/IEC 62366-1:2015 Medical devices - Part 1: Application of Usability Engineering to Medical Devices (FDA Recognition Number 5- 114)

**VII Performance Characteristics (if/when applicable):**

**A Analytical Performance:**

1. Precision/Reproducibility:

Not applicable.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Accuracy (Instrument):

Not applicable.

5. Carry-Over:

Not applicable.

**B Other Supportive Instrument Performance Characteristics Data:**

- a. Human Factors: Human factors validation tests were conducted with the app installed on a compatible mobile device. The final device design was evaluated in the summative study performed with 70 representative participants from four distinct user groups interacting with the device in a simulated use environment. Those four user groups are:

- The adult responsible for their own insulin therapy, ages over 19, with representative proportion of pump users and non-pump users with Android or iOS smartphones.
- The pediatric responsible for their own insulin therapy, ages 12-19, with representative proportion of pump users and non-pump users with Android or iOS smartphones.
- The pediatric who shares responsibility for their insulin therapy with a parent or caregiver, ages 8-15, with representative proportion of pump users and non-pump users with Android or iOS smartphones.
- The pediatric whose parent is responsible for their child's insulin therapy, ages 6-11, with representative proportion of pump users and non-pump users with Android or iOS smartphones.

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 device could be used safely by intended users in the intended use environment when used in combination with a digitally connected device.

- Data Logging: Software verification testing has demonstrated the device records timestamped critical events, including information related to its state, user inputs, and device settings, as required by the special controls. The mobile application will retrieve history logs from the pump as necessary. The mobile application uploads history logs from the pump to the Connected Health Service. The mobile app operates similarly to the existing pump history log uploader; it uploads logs that the Connected Service does not have yet.
- Interoperability: The Interoperable Device Verification and Validation activities were performed to ensure the t:slim X2 pump software was compatible with the t:connect mobile app and met the interoperable device special controls. These activities included: Battery Life Testing, RF communications Range Testing, and Penetration Testing.
- Cybersecurity: Tandem provided a software bill of materials, which provided details on all software used in the device and the hardware platform that the device was installed on. This included all manufacturer-developed, commercially licensed, open source, and off-the-shelf software components (including firmware as relevant), along with an identification of the hardware runtime environment in which each resides, with relevant version and/or model information, as well as details on whether each component was actively supported by its manufacturer or legacy licensed. Tandem completed various verification various verification and validation activities including penetration testing.

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.