DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 25, 2016

Tandem Diabetes Care, Inc.
Mr. Michael Sarrasin
Senior Director of Regulatory Affairs
11045 Roselle Street
San Diego, California 92121

Re: K162080
Trade/Device Name: t:slim® Insulin Delivery System, t:flex™ Insulin Delivery System, Tandem® Device Updater™ System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, MRZ
Dated: September 27, 2016
Received: September 28, 2016

Dear Mr. Sarrasin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*

K162080

Device Name

t:slim® Insulin Delivery System, t:flex™ Insulin Delivery System, The Tandem® Device Updater™ System

Indications for Use *(Describe)*

The t:slim® Insulin Delivery System is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 6 years of age and greater. The device is indicated for use with NovoLog® or Humalog® U-100 insulin.

The t:flex™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater. The device is indicated for use with NovoLog® or Humalog® U-100 insulin.

The Tandem® Device Updater™ System consists of software which allows for communication between a computer and a t:slim® or t:flex™ Insulin Delivery System. It allows for remote software installation and update of a Tandem Insulin Delivery System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510(k) SUMMARY

## Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tandem Diabetes Care, Inc.
11045 Roselle Street
San Diego, CA 92121
Phone: 858-366-6900
Facsimile: 858-362-7070

Contact Person: Michael Sarrasin
Contact Email: MSarrasin@tandemdiabetes.com

Date Prepared: October 25, 2016

## Name of Device

t:slim® Insulin Delivery System
t:flex™ Insulin Delivery System
The Tandem® Device Updater™ System

## Common or Usual Name

Insulin infusion pump

## Classification Name

Infusion Pump per 21 CFR 880.5725

## Product Codes

LZG, Insulin Infusion Pump
MRZ, Infusion Pump Accessories

## Predicate Devices

Primary Predicate Device:
Tandem Diabetes Care, Inc. t:slim® Insulin Delivery System, t:flex® Insulin Delivery System, Tandem Device Updater (K160428)

Reference Predicate Device:
Tandem Diabetes Care, Inc. t:slim® Insulin Delivery System (K160056)

## Purpose of the 510(k) notification

The purpose of this 510(k) is to describe modified indications for use of the t:slim® Insulin Delivery System. The indications for use of the t:slim Insulin Delivery System under this 510(k) combines the indications for use of the t:slim Insulin Delivery System cleared under K160056 with the updated software and accessories cleared for the t:slim Insulin Delivery System cleared under K160482. The t:slim Insulin Delivery System was cleared under K160482 with updated software and with the Tandem Device Updater System accessory for ages 12 years and older. The t:slim Insulin Delivery System was cleared under K160056 for ages 6 years and older without the software update or Tandem Device Updater System accessory of K160482. This 510(k) combines the updated

software, Tandem Device Updater System accessory, and indication for 6 years and older for the t:slim Insulin Delivery System

Minor device hardware modifications were also included for the t:slim Insulin Delivery System and t:flex Insulin Delivery System in this 510(k).

**Device Description**

The t:slim® and t:flex™ Insulin Delivery Systems facilitate the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The accessory Tandem Device Updater™ System is comprised of a personal computer application, a web server, an embedded firmware application, and a Tandem pump (t:slim or t:flex). The goal of the Tandem Device Updater System is to provide a secure process for software installation and update.

**Intended Use**

The t:slim® Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 6 years of age and greater. The device is indicated for use with NovoLog® or Humalog® U-100 insulin.

The t:flex™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater. The device is indicated for use with NovoLog® or Humalog® U-100 insulin.

The Tandem® Device Updater™ System consists of software which allows for communication between a computer and a t:slim® or t:flex™ Insulin Delivery System. It allows for remote software installation and update of a Tandem Insulin Delivery System.

**Technological Characteristics**

The t:slim and t:flex Insulin Delivery Systems have the same technological characteristics as the respective predicate devices. Both Systems, like the predicates, consist of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:slim and t:flex Pump"); (2) a dedicated disposable 3.0 mL (300 units) and 4.8 mL (480 units) insulin cartridge, respectively; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a sterile syringe and needle (for cartridge filling) an AC power supply and DC car adapter power supply with USB.

Minor technological differences when compared to the primary predicate device include minor modifications to the wake button and updates to the fuel gauge registers. There are no software changes when compared to the primary predicate device.

The Tandem Device Updater ™ System is identical to the previously cleared Tandem Device Updater System. The products both allow for communications between a computer and an infusion pump. The software programs provide software installation and updates.

**Performance Data**

Software verification and validation testing was performed per FDA's guidance document, *Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions Guidance*, issued on December 2, 2014.

Hardware changes were supported by verification testing per previously established acceptance criteria. Testing includes tactile feedback, fluid ingress, performance testing, and simulated use.

Previously completed testing to support substantial equivalence determination included pump software, hardware, EMC testing and electrical safety testing. Software testing was previously performed on the version of software which is the subject of this 510(k). Tandem previously completed validation of the Tandem Device Updater System's user interface through human factor formative and summative studies. Pediatric Human Factors testing was completed for the t:slim Insulin Delivery System to support the use of the device in individuals 6 years of age and greater. Human Factors testing included a validation study for children between ages 6-12 in order to assess the intended user population's ability to identify, interpret, and understand the t:slim Insulin Delivery System's alarms. Labeling, warnings and precautions provide further information regarding the risks of the device for pediatric users.

An updated safety assurance case was provided for the t:slim and t:flex Insulin Delivery System as recommended in the FDA's guidance document, *Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions Guidance*, issued on December 2, 2014.

The assurance case defined the device system, including the indications for use, patient types, users, use conditions, environments of use, and list of specific devices covered by the assurance case with associated design specification and labeling documentation. The supporting assurance arguments covered the following attributes:

- Demonstrate acceptability of risk mitigations
- Demonstrate adequate device reliability
- Demonstrate adequate design verification and validation of device specifications

The assurance case included mitigations of risks related to the following hazards:

- Operational Hazards
- Environmental Hazards
- Electrical Hazards
- Hardware Hazards
- Software Hazards
- Mechanical Hazards
- Biological and Chemical Hazards
- Use Hazards

Additions to the safety assurance case from the predicate devices' cases included the LCD screen reports, Tandem Device Updater for use with the t:slim pump, updated wake button, updated fuel gauge register, and the updated t:slim indications for use.

**Substantial Equivalence**

Tandem t:slim® and t:flex™ Insulin Delivery Systems have the same intended use, the same principles of operation, and the same technological characteristics as the previously cleared predicate devices. The purpose of this 510(k) is to introduce minor hardware changes to t:slim and t:flex Systems and to include individuals 6 years of age and greater in the indications for use for the t:slim Insulin Delivery System. The t:slim Insulin Delivery System was cleared under K160056 with indications for 6 years and greater, but was cleared separately under K150482 with an updated

version of software and the Tandem Device Updater System accessory. This 510(k) merges the indications for use of 6 years and greater with the updated software and Tandem Device Updater accessory for the t:slim Insulin Delivery System. The verification and validation testing, including human factors testing, confirms that the t:slim® and t:flex™ Insulin Delivery Systems and Accessories are substantially equivalent to the predicates.