DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 13, 2016

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

Re: K160482
Trade/Device Name: t:slim® Insulin Delivery System, t:flex™ Insulin Delivery System, The Tandem® Device Updater™ System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, MRZ
Dated: June 13, 2016
Received: June 13, 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 yours,

for Erin I. Keith, M.S.
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 below.

510(k) Number *(if known)*
K160482

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 12 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K160482

Tandem® Diabetes Care, Inc.

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

Tandem Diabetes Care, Inc.
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Contact Person: Michael Sarrasin
Contact Email: MSarrasin@tandemdiabetes.com

Date Prepared: July 13, 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 Device

Tandem Diabetes Care, Inc. t:slim® Insulin Delivery System (K141758)
Tandem Diabetes Care, Inc. t:flex™ Insulin Delivery System (K143189)
Medfusion® Model 4000 Syringe Infusion Pump with the PharmGuard® Toolbox2 Medication Safety Software (K111386).

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 consists of software which allows for communications between a computer and a Tandem Diabetes Care, Inc. Insulin Delivery System. The Tandem Device Updater™ allows for software installation and update.

The Tandem Device Updater System is comprised of a personal computer application, a web server (HAL), an embedded firmware application (Homer), and a Tandem pump (t:slim or t:flex). The goal of the Tandem Device Updater System is to provide a process for the user to perform updates to the firmware components of a Tandem pump. The Tandem Device Updater System provides communication security consisting of message authentication and encryption, two commonly used methods to secure communication protocols (i.e. USB). Communication between the pump and the Tandem Device Updater System can only occur while the pump is connected to a computer via USB cable.

The *HAL Web Server* (HAL) is a web server that is responsible for storing and delivering the firmware components of a pump.

The *Homer Firmware Application (Homer*) is a software application which is part of Tandem Device Updater System that runs on the main MCU incorporated in the pump. Homer is used to update the Bootloader Software in each MCU, essentially rewriting the contents in the flash memory of the MCU. In addition to updating the Bootloader Software, Homer will provide an interface for the secure exchange of security keys during the enabling of communication security. Homer authenticates critical messages received from the PC application.

The Tandem pumps (i.e., t:flex and t:slim described above) incorporate three separate microcontroller units (*MCU*s), and each MCU runs two separate pieces of firmware, known as the *Bootloader Software,* and *Application Software*. The Application Software running on the main MCU, utilizes a graphics library to generate the screens for the pump display. The Tandem Device Updater downloads files from Tandem and installs them on the pump. All binary images for use on the pump transmitted by the Tandem Device Updater are encrypted.

The software components on the pump that may be updated by the Tandem Device Updater System include: the Bootloader Software stored in each MCU, the Application Software stored in each MCU, and the graphics library files stored in the nonvolatile flash memory module.

The software version of the t:slim and t:flex Insulin Delivery Systems for this submission is version 4.3.5.1. The software version of the Tandem Device Updater System for this submission is version 1.0.

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 12 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.

Modifications of Intended Use Compared to Predicate

The intended use statements of the t:slim and t:flex Insulin Delivery Systems have been modified to include a statement of the drug and drug concentration to be delivered by the pumps. This modification does not change the predicate intended use since the t:slim and t:flex Insulin Delivery System predicate labeling included statements that only NovoLog or Humalog U-100 insulin is to be used with the pumps. No functional characteristics were changed in response to the modification of the intended use statement.

The intended use of the Tandem Device Updater System is very similar to that of the predicate device Medfusion Model 4000 Syringe Infusion Pump with the PharmGuard® Toolbox2 Medication Safety Software. Both the Tandem Device Updater System and the PharmGuard Toolbox2 Medication Safety Software contain software intended to provide software updates to their respective indicated infusion pumps by allowing communication between a computer and an infusion pump.

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 predicate device include the addition of an LCD screen, alternate USB cables, and cartridge box quantity of 2. Minor software changes were made to the t:slim and t:flex pumps including an updated homing algorithm, support for the LCD screen, authentication and encryption in the software, reference to the software version by a user friendly name, suppress fuel gauge learning after soft reset (but force after shelf mode emergence), and to address previously identified unresolved software anomalies. The t:slim and t:flex Insulin Delivery Systems software updates are for version 4.3.5.1.

The Tandem Device Updater ™ System is similar in design, function and intended use to the Medfusion® 4000 wireless syringe infusion pump with the PharmGuard® Toolbox 2 Medication Safety Software, specifically the SureLink Remote Support Software portion. The products both allow for communications between a computer and an infusion pump. The software programs provide software installation and updates.

Performance Data

An assurance case was provided for the t:slim and t:flex Insulin Delivery Systems 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 stated goal of the t:slim/t:flex assurance case is:

- The safety risk resulting from use of t:slim/t:flex pump is reduced to acceptable levels and is As Low As Reasonably Practicable (ALARP) through use of mitigating technologies and the risks are substantially equivalent to the predicate device.

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

The following evidence was included in the assurance case:

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. Previously completed testing to support substantial equivalence determination included pump software, hardware, EMC testing and electrical safety testing. Software testing was performed on the version of software which is the subject of this 510(k).

An assurance case was provided for the Tandem Device Updater System accessory 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 stated goal of the Tandem Device Updater System assurance case is:

- The safety risk resulting from use of Tandem Device Updater is reduced to acceptable levels and is As Low As Reasonably Practicable (ALARP) through use of mitigating technologies and the risks are substantially equivalent to the predicate device.

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:

- Software Hazards
- Use Hazards

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.

Tandem completed validation of the Tandem Device Updater System's user interface through human factor formative and summative studies.

Cybersecurity information including encryption, authentication, threat detection, penetration testing, operating system support, and a risk analysis were provided to address the cybersecurity risks of the Tandem Device Updater.

The t:slim/t:flex safety assurance cases include risk mitigation strategies addressing the pump interaction with other software/devices, including the Tandem Device Updater System. The Tandem Device Updater System safety assurance case includes risk mitigations involving all interactions between the Tandem Device Updater System and the Tandem Pumps (i.e. t:slim and t:flex) and the user.

Substantial Equivalence

Tandem t:slim® and t:flex™ Insulin Delivery Systems have the same intended use and indications for use (updated to explicitly state the insulin to be used), the same principles of operation, and similar technological characteristics as the previously cleared predicate devices. The purpose of this 510(k) is to introduce minor software changes to t:slim and t:flex as well as to introduce the Tandem Device Updater™. 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.