DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 9,2015

Tandem Diabetes Care, Incorporated
c/o Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 1910

Re: K143189
Trade/Device Name: t:flex Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: November 5, 2014
Received: November 5, 2014

Dear Ms. Hogan:

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" (21CFR 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,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
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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)*

Device Name

t:flex™ Insulin Delivery System

Indications for Use *(Describe)*

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.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K143189

Tandem Diabetes Care, Inc. t:flex™ Insulin Delivery System

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

Tandem Diabetes Care, Inc.
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Contact Person: John Sheridan
Contact Email: jsheridan@tandemdiabetes.com

Date Prepared: November 5, 2014

Common or Usual Name

Insulin infusion pump

Classification Name

Infusion Pump per 21 CFR 880.5725

Predicate Devices

Tandem Diabetes Care, Inc. t:slim® Insulin Delivery System (K141758)

Purpose of the 510(k) notification

The t:flex™ Insulin Delivery System is a modification to the previously cleared t:slim® Insulin Delivery System. Specifically, t:flex™ System includes a larger cartridge (4.8 mL vs 3.0 mL) to accommodate patients with higher needs of daily insulin intake.

Intended Use

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.

Device Description

The t:flex™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The t:flex System, like the predicate device, consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump ("t:flex Pump" or "Pump");
2. a dedicated, disposable 4.8 mL (480 unit) insulin cartridge ("cartridge");

3. an UnoMedical Comfort™ Infusion Set (K051264), or an equivalently FDA cleared infusion set ("infusion set"); and
4. accessories, including a 5 mL sterile syringe and 26 gauge sterile needle, as well as an AC power supply and DC car adapter power supply with USB for charging the Pump's internal battery, cartridge Instructions for Use, and User's Guide.

The t:flex Pump is a battery operated infusion pump capable of both basal and bolus delivery of insulin. It utilizes a motor-driven mechanism to deliver insulin from within a disposable cartridge, through an infusion set, into a patient's subcutaneous tissue. As with current insulin infusion pumps on the U.S. market, the desired timing and quantity of the insulin delivery is programmed by the user (*i.e.*, the patient). The graphical user interface ("GUI") of the t:flex Pump is a capacitive touch screen that displays information used to control the t:flex System. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge.

The t:flex cartridge is a single-use device, individually packaged and sealed, and is provided sterile. The cartridge attaches to the t:flex Pump and is designed to hold up to 4.8 mL, or 480 units of insulin. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge. The Pump has a pressure measurement sensor to estimate the volume of insulin in the insulin reservoir by measuring air pressure in the cartridge. This information is used to provide feedback to the software to determine the insulin volume, detect occlusions and cartridge removal.

Technological Characteristics

The t:flex Insulin Delivery System has the same technological characteristics as the predicate device. The t:flex System consists of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:flex Pump"); (2) a dedicated disposable 4.8 mL (480 unit) insulin cartridge; (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.

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 Draft Guidance*, issued on April 23, 2010 ("Draft Guidance"). Hardware changes were supported by verification testing per previously established acceptance criteria. Completed testing to support substantial equivalence determination included pump software, hardware, aged mechanical verification, pump aged water ingress, average current consumption testing, battery runtime verification, EMC testing and electrical safety testing. Cartridge testing includes cartridge verification testing, mechanical testing and package and distribution testing. Tandem completed verification of the t:flex System's user interface through human factor formative and summative studies.

Substantial Equivalence

The t:flex System has the same intended use and indications for use, the same principles of operation, and same technological characteristics as the previously cleared predicate device. The purpose of this 510(k) is to introduce a pump with a larger insulin cartridge, minor software and hardware changes. The changes made to the device are those necessary to accommodate the

larger insulin cartridge. The verification and validation testing, including human factors testing, confirms that the t:flex System is substantially equivalent to its predicate.