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

July 25, 2016

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

Re: K160056
Trade/Device Name: t:slim Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: July 5, 2016
Received: July 6, 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,

Tina Kiang
-S

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)*
K160056

Device Name
t:slim® Insulin Delivery 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.

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.

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 K160056

Tandem Diabetes Care, Inc.

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

Tandem Diabetes Care, Inc.
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Phone: 858-366-6900
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Contact Person: Michael Sarrasin
Contact Email: MSarrasin@tandemdiabetes.com

Date Prepared: July 21, 2016

Name of Device

t:slim® Insulin Delivery System

Common or Usual Name

Insulin infusion pump

Classification Name

Infusion Pump per 21 CFR 880.5725

Product Code

LZG, Insulin infusion Pump

Predicate Devices

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

Purpose of the 510(k) notification

The purpose of this 510(k) is to describe modified indications for use for the t:slim® Insulin Delivery System

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.

Device Description

The t:slim® 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 scope of this Traditional 510(k) is limited to expansion of the indications for use to include individuals 6 years of age and greater. The device is indicated for use with NovoLog or Humalog U-100 insulin. No changes have been made to the device components to accommodate the modified indications for use.

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

1. a software-controlled, programmable insulin infusion pump ("t:slim Pump" or "Pump");
2. a dedicated, disposable 3.0 mL (300 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 3 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:slim Pump is a battery operated infusion pump capable of both basal and bolus delivery of insulin. The Pump 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:slim Pump is a touch screen that displays information used to control the t:slim System. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge.

Identical to the predicate device, the t:slim cartridge is a single-use device, individually packaged and sealed, and is provided sterile. The cartridge attaches to the t:slim Pump and is designed to hold up to 3.0 mL (300 units) of insulin. Both in the predicate and in the device that is the subject of this 510(k) notice, 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:slim Insulin Delivery System that is the subject of the modified indication in this 510(k) submission has the same technological characteristics as the predicate device. The 510(k) device and the predicate Systems both consist of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:slim Pump"); (2) a dedicated disposable 3.0 mL (300 units) 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

A summary of peer reviewed literature supports the use of CSII in ages 6 through 11.

A safety assurance case was provided for the t:slim 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 assurance case is:

- The safety risk resulting from use of t:slim 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 to support the modifications of the subject device's indications for use in comparison to the predicate:

Human Factors testing supports substantially equivalent use of the device in individual's from 6 years of age and greater. Updated labeling, warnings, and precautions provide further information regarding the risks of the device for pediatric users.

Substantial Equivalence

The current t:slim System has the same intended use and very similar indications for use compared to the predicate device. The only change is the modification of the indications to include users as young as 6 years of age. The system also has identical technological characteristics. Human factors testing confirms that the current t:slim System, when indicated for younger users, continues to perform in a substantially equivalent manner.