K111210

NOV - 9 2011

510(k) SUMMARY
Tandem Diabetes Care, Inc.'s t:slim™ Insulin Delivery System

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

Tandem Diabetes Care™, Inc.
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Date Prepared: August 3, 2011

Common or Usual Name / Classification Regulation

Insulin Pump / 21 C.F.R. 880.5725

Predicate Devices

Medtronic MiniMed's 508 Insulin Pump (K990801)

Nipro Diabetes Systems, Inc.'s Amigo Insulin Pump (K071613)

Intended Use / Indications for Use

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, for individuals 12 years of age and greater.

Device Description

The t:slim™ Insulin Delivery System ("t:slim System") consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump ("t:slim Pump" or "Pump"),
2. a dedicated, disposable 3mL (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 Becton Dickenson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC 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. 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 end user (*i.e.*, the patient). The graphical user interface on the t:slim Pump is a capacitive touch screen that is overlaid on an organic light emitting diode ("OLED") 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.

Cartridges are individually packaged and sealed, and provided sterile. The cartridge attaches to the t:slim Pump and is designed to hold up to 3 mL, or 300 units, of insulin. The cartridge has been tested for insulin compatibility with two types of rapid-acting U-100 insulin (Humalog® and NovoLog®) and determined to be insulin compatible as demonstrated by the performance data submitted in this 510(k) application.

Technological Characteristics

The t:slim System consists 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 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories.
The t:slim System and the cartridge materials of construction are commonly used in electro-mechanical medical equipment.

Performance Data

Tandem Diabetes Care™, Inc. ("Tandem") completed the appropriate validation and verification activities required by the *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"). Pump validation and verification activities included: software, hardware, mechanical, environmental conditioning, water ingress, simulated aging testing, electrical safety and electromagnetic compatibility testing. Cartridge verification activities included: mechanical testing, environmental conditioning, simulated aging, biocompatibility and insulin compatibility testing. System performance testing was conducted to ensure that the t:slim System meets its intended requirements. Tandem completed verification of the t:slim System's user interface through a series of Formative Studies. Testing was completed to relevant standards, as applicable.

The following performance and safety tests were conducted to evaluate the t:slim System:

- Pump Flow Rate Accuracy,
- Pump Bolus Accuracy,
- Battery Indication Performance,
- Cartridge Depletion and Low Insulin Alert,
- Summative Human Factors Study,
- Cartridge Performance Validation,
- Pump Environmental and Operational Life Validation,
- Flow Rate Accuracy for Minimum Flow Rate,
- Flow Rate Accuracy after Change in the Infusion Rate or Bolus Dose,
- Insulin Stability Study,

- Minimum Bolus Accuracy,
- Occlusion Alarm Test, and
- Free Fall Test and Vibration Tests.

In all instances, the t:slim Insulin Delivery System functioned as intended and testing results observed were as expected.

Human Factors Validation

Validation of the User interface was accomplished through a prospective non-randomized, multicenter Investigational Human Factors Summative Study. In this Summative Study, a total of 53 patients ranging in age from 12-74 years old participated in representative training, then exercised all tasks critical for the safe operation of the t:slim System in the home use ambulatory environment. This Study demonstrated that the t:slim System can be used without critical errors that could lead to user harm. Through this comprehensive series of tests and system risk analysis, the Company has demonstrated that the t:slim System satisfies all functional performance, safety requirements, and user meets its intended use, and is safe for the intended user population.

Assurance Case Reports

Tandem has demonstrated the t:slim System is safe and effective as intended, through the use of *Assurance Case Reports* as recommended in the Draft Guidance.

Substantial Equivalence

The t:slim System is as safe and effective as Medtronic MiniMed's 508 Insulin Pump (K990801) and Nipro Medical Corporation's Amigo Insulin Pump (K071613), as demonstrated by performance data. It has the same intended use/indications for use, and similar technological characteristics and principles of operation, and the minor technological differences between the t:slim System and its predicate devices raise no new issues of safety or effectiveness. Thus, the t:slim System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Don Canal
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Re: K111210
Trade/Device Name: t:slim Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: November 7, 2011
Received: November 7, 2011

Dear Mr. Canal:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111210

Device Name: **t:slim™ Insulin Delivery System**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/9/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111210