Tandem Diabetes Care, Inc.'s t:connect Data Management System

Common or Usual Name / Classification Regulation
The t:connect Data Management System is an accessory to the Tandem t:slim Insulin Pump system which is classified under 21 C.F.R. 880.5725, Pump, Infusion, Insulin, Class II, Product Code, LZG.

Predicate Devices
- Medtronic MiniMed Diabetes Data Management System (K032164)
- Aidera Diasend System (K101806)

Intended Use / Indications for Use
The t:connect Diabetes Management Application is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care insulin pumps, their care givers, and their healthcare providers in home and clinical settings. The t:connect Application supports diabetes management through the display and analysis of information downloaded from Tandem Diabetes Care insulin pumps and specified blood glucose meters.

Device Description
The Tandem t:connect is a web based software system which allows pump users, care givers and healthcare professionals to view data retrieved from a Tandem Ambulatory Insulin Pump and Blood Glucose meters. t:connect is comprised of a Data Uploader, a Web Application, a Secure Web and Database Server, and an Admin Web Application.

The t:connect Data Uploader is a client based software application installed on the pump user's personal computer. Using a USB cable connecting the pump to a personal computer, the application uploads pump data to a secure online database server through a secure, encrypted, internet connection. The t:connect Data Uploader also uploads data from a limited set of Blood Glucose meters.

The t:connect Web Application is a reporting application that provides users with the ability to view and print (to PDF) both tabular and graphical reports representing the data uploaded to the online database. The t:connect Web Application is the "t:connect Website" shown in Figure 1.

The t:connect Web and Database Server is an application that runs on the secure server. Data displayed on the t:connect Web Application is retrieved from the secure Database
"intermediary" providing an extra layer of security and restricted access to the Database Server.

For both the Data Uploader and the Web Application, users are authenticated against a "pump and patient" database to insure maximum security and secure access to only their data.

The Admin Web Application is an application used to manage accounts. It also allows holders of certain types of accounts to Logon As User to the t:connect Web Application as other users.

t:connect does not have the ability to modify any therapy provided by or parameters internal to the devices it communicates with. t:connect only reads data from these devices.

The major functions of the device include:

- Retrieve History Log data from the pump and transmit to the database server
- Retrieve History Log data from various BG meters and transmit to the database server
- Retrieve Diagnostic information from the pump and transmit to the database server
- Provide a means to view the pump's complete history log
- Retrieve Pump Settings from the pump for easy viewing by the user
- Display Therapy Data textually and graphically
- Manage User Accounts for retrieving and viewing pump data
- Generate Notifications for the user
- Print reports to PDF
- Export data for use in generating customer reports using other software applications
- Provision of user help
- Administrator functionality related to creation and managing user accounts

Performance Data
Tandem has completed the necessary performance testing to verify that the design input requirements have been met. Software verification and validation testing was completed to demonstrate the t:connect Data Management System meets the established design inputs and its intended use.

1. Software Validation Report
2. Software Verification Report
3. GUI Verification Test Report
4. Human Factors Research Validation Report
5. Software V&V Report
6. Labeling Verification Test report
7. Final Traceability Report
8. Risk Management Summary

Clinical and Human Factors Evaluation
Tandem completed three formative human factors studies and a summative human factors validation test using 30 participants. Data from these formative studies were used to refine the graphical user interface of the t:connect Data Management System. A summative human factors validation test was completed with 30 participants.

A total of 30 representative adult users stratified into two population segments: (15) healthcare professionals and (15) type 1 diabetics. The participants completed a set of representative task scenarios presented to them in as efficient and timely a manner as
possible. They were asked to provide feedback regarding the usability and acceptability of the t:connect software system. Participants received 30 minutes of training prior to the session from a Certified Diabetes Educator.

The participant's interaction with the system was observed by the moderator seated in an observation room and were audio/video-recorded using the Morae usability software suite, which captured participant facial gestures and speech, as well as system interaction and data-logging. The Summative study did not reveal any safety related issues.

Assurance Case Reports

Tandem has demonstrated the t:connect Data Management System is safe and effective as intended, through the use of Assurance Case Reports.

Substantial Equivalence

The t:connect Data Management System is as safe and effective as the Medtronic MiniMed Diabetes Data Management System (K032164) and the Aidera Diasend System (K01806), as demonstrated by performance data and equivalence analysis. 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:connect Data Management System and its predicate devices raise no new issues of safety or effectiveness. Thus, the t:connect Data Management System is substantially equivalent to the predicate devices.

Comparison of Technological Characteristics

<table>
<thead>
<tr>
<th>Element of Comparison</th>
<th>Tandem Diabetes t:connect</th>
<th>Medtronic DMS (K032164)</th>
<th>Aidera Diasend (K101806)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Type</td>
<td>Web App</td>
<td>Web App</td>
<td>Web App</td>
</tr>
<tr>
<td>Pie Charts of BG &amp; Insulin</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Modal Day BG Charts</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Charts of Basal &amp; Bolus Delivery</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>User Selectable Date Ranges</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Logbook</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Displays Device Settings</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>“Print Report” Option</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Allows User to Annotate Therapy Data</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dashboard Summary</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Notifications</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Exports to Excel Compatible Files</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supported Insulin Pumps</td>
<td>Tandem</td>
<td>Medtronic</td>
<td>Multiple</td>
</tr>
<tr>
<td>Element of Comparison</td>
<td>Tandem Diabetes t:connect</td>
<td>Medtronic DMS (K032164)</td>
<td>Aiedera Diasend (K101806)</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------</td>
<td>-------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Supports J&amp;J/LifeScan BG Meters</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supports Abbott BG Meters</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supports Roche BG Meters</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supports Additional BG Meters</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supports Microsoft OS</td>
<td>Win XP</td>
<td>Win XP</td>
<td>Win XP</td>
</tr>
<tr>
<td></td>
<td>Win Vista</td>
<td>Win Vista</td>
<td>Win Vista</td>
</tr>
<tr>
<td></td>
<td>Win 7</td>
<td>Win 7</td>
<td>Win 7</td>
</tr>
<tr>
<td>Supports Apple Mac OS</td>
<td>OSX 10.5</td>
<td>OSX 10.5</td>
<td>OSX 10.5</td>
</tr>
<tr>
<td></td>
<td>OSX 10.6</td>
<td>OSX 10.6</td>
<td>OSX 10.6</td>
</tr>
<tr>
<td></td>
<td>OSX 10.7</td>
<td>OSX 10.7</td>
<td>OSX 10.7</td>
</tr>
<tr>
<td>Supported Browsers</td>
<td>IE</td>
<td>IE</td>
<td>510(k) Does Not Specify</td>
</tr>
<tr>
<td></td>
<td>Safari</td>
<td>Safari</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Firefox</td>
<td>Firefox</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chrome</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
February 22, 2013

Ms. Nora C.R. York
Tandem Diabetes Care, Incorporated
11045 Roselle Street Suite 200
SAN DIEGO CA 92121

Re: K122361
Trade/Device Name: Tandem t: connect Data Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: February 12, 2013
Received: February 13, 2013

Dear Ms. Nora C.R. York:

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" (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 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,
Respiratory, 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): K122361

Device Name: Tandem t:connect Data Management System

Indications for Use:

The t:connect Diabetes Management Application is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care insulin pumps, their caregivers, and their healthcare providers in home and clinical settings. The t:connect Application supports diabetes management through the display and analysis of information downloaded from Tandem Diabetes Care insulin pumps and specified blood glucose meters.

Prescription Use AND/OR Over-The-Counter Use

X (Part 21 CFR 801 AND/OR (21 CFR 801 Subpart Subpart D) C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

Richard C. Chapman 2013.02.21 11:58:51 -05'00'

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

510(k) Number: K122361