December 3, 2019

Tandem Diabetes Care, Inc.
Michael Sarrasin
Senior Director of Regulatory and Clinical Affairs
11075 Roselle Street
San Diego, CA 92121

Re: DEN180058
Trade/Device Name: t:Slim X2 insulin pump with interoperable technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG
Dated: October 25, 2018
Received: October 29, 2018

Dear Michael Sarrasin:

This letter corrects our classification order dated February 14, 2019.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the t:Slim X2 insulin pump with interoperable technology, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the t:Slim X2 insulin pump with interoperable technology, and substantially equivalent devices of this generic type, into Class II under the generic name Alternate controller enabled infusion pump.

FDA identifies this generic type of device as: **Alternate controller enabled infusion pump**.

> An alternate controller enabled infusion pump (ACE pump) is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 29, 2018, FDA received your De Novo requesting classification of the t:Slim X2 insulin pump with interoperable technology. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the t:Slim X2 insulin pump with interoperable technology into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the t:Slim X2 insulin pump with interoperable technology can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risk	**Mitigation Measures**
Patient harm due to inadequate drug delivery accuracy that leads to over infusion or under infusion of drug.	Basal and bolus drug delivery accuracy validation testing Device use life reliability testing Design mitigations to prevent cross-channeling Validated and traceable risk control measures for identified hazards
Patient harm due to undetected pump occlusions that pose risk of under infusion of drug.	Hazard detection (e.g., drug occlusion) validation testing

Identified Risk	Mitigation Measures
Patient harm due to incompatibility between the drug and the pump that may lead to over infusion or under infusion of drug, or exposure to harmful substances leached from pump materials into the infused drug solution.	Drug compatibility testing
Inability to provide appropriate treatment due to loss of communication with digitally connected alternate pump controller devices.	Validated communication specifications, processes, and procedures with digitally connected devices
Commands from the digitally connected alternate pump controller devices that conflict with existing pump commands may lead to unintended over or under infusion of drug.	Validated communication specifications, processes, and procedures with digitally connected devices Validated failsafe design features
Conflicting interfaces resulting in over or under delivery.	Validated communication specifications, processes, and procedures with digitally connected devices Validated failsafe design features
Patient harm due to insecure transmission of data.	Validated communication specifications, processes, and procedures with digitally connected devices
Patient harm due to inability to determine source of dosing error when used in an integrated system.	Validated data logging capability
Patient harm due to exposure to hazardous and non-biocompatible materials or pathogens.	Biocompatibility testing Validation of reprocessing procedures
Patient harm due to data transmission interference/electromagnetic disturbance.	Electrical safety, electromagnetic compatibility, and radio frequency wireless safety testing
Patient harm due to incorrect use of pump, operational, and/or use-related errors.	Human Factors testing Transparent pump performance descriptions in labeling

In combination with the general controls of the FD&C Act, the Alternate controller enabled infusion pump is subject to the following special controls:

1. Design verification and validation must include the following:

    a. Evidence demonstrating that device infusion delivery accuracy conforms to defined user needs and intended uses and is validated to support safe use under actual use conditions.
        i. Design input requirements must include delivery accuracy specifications under reasonably foreseeable use conditions, including ambient temperature changes, pressure changes (e.g., head-height, backpressure, atmospheric), and, as appropriate, different drug fluidic properties.

   ii. Test results must demonstrate that the device meets the design input requirements for delivery accuracy under use conditions for the programmable range of delivery rates and volumes. Testing shall be conducted with a statistically valid number of devices to account for variation between devices.

   b. Validation testing results demonstrating the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (e.g., occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes. Hazard detection must be appropriate for the intended use of the device and testing must validate appropriate performance under the conditions of use for the device.
   c. Validation testing results demonstrating compatibility with drugs which may be used with the pump based on its labeling. Testing must include assessment of drug stability under reasonably foreseeable use conditions which may affect drug stability (e.g., temperature, light exposure, or other factors as needed).
   d. The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible. This shall include chemical and particulate characterization on the final, finished, fluid contacting device components demonstrating that risk of harm from device-related residues is reasonably low.
   e. Evidence verifying and validating that the device is reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.
   f. The device must be designed and tested for electrical safety, electromagnetic compatibility, and radio frequency wireless safety and availability consistent with patient safety requirements in the intended use environment.
   g. For any device that is capable of delivering more than one drug, the risk of cross-channeling drugs must be adequately mitigated.
   h. For any devices intended for multiple patient use, testing must demonstrate validation of reprocessing procedures and include verification that the device meets all functional and performance requirements after reprocessing.

2. Design verification and validation activities must include appropriate design inputs and design outputs that are essential for the proper functioning of the device that have been documented and include the following:
   a. Risk control measures shall be implemented to address device system hazards and the design decisions related to how the risk control measures impact essential performance shall be documented.
   b. A traceability analysis demonstrating that all hazards are adequately controlled and that all controls have been validated in the final device design.

3. The device shall include validated interface specifications for digitally connected devices. These interface specifications shall, at a minimum, provide for the following:
   a. Secure authentication (pairing) to external devices.
   b. Secure, accurate, and reliable means of data transmission between the pump and connected devices.
   c. Sharing of necessary state information between the pump and any digitally connected alternate controllers (e.g., battery level, reservoir level, pump status, error conditions).
   d. Ensuring that the pump continues to operate safely when data is received in a manner outside the bounds of the parameters specified.
   e. A detailed process and procedure for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.

4. The device must include appropriate measures to ensure that safe therapy is maintained when communications with digitally connected alternate controller devices is interrupted, lost, or re-established after an interruption (e.g., reverting to a pre-programmed safe drug delivery rate). Validation testing results must demonstrate that critical events that occur during a loss of communications (e.g., commands, device malfunctions, occlusions, etc.) are handled appropriately during and after the interruption.

5. The device design must ensure that a record of critical events is stored and accessible for an adequate period to allow for auditing of communications between digitally connected devices, and to facilitate the sharing of pertinent information with the responsible parties for those connected devices. Critical events to be stored by the system must, at a minimum, include:
   a. A record of all drug delivery
   b. Commands issued to the pump and pump confirmations
   c. Device malfunctions
   d. Alarms and alerts and associated acknowledgements
   e. Connectivity events (e.g., establishment or loss of communications)

6. Design verification and validation must include results obtained through a human factors study that demonstrates that an intended user can safely use the device for its intended use.

7. Device labeling must include the following:
   a. A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate.
   b. A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.
   c. A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: number of bolus doses with volume that is <25%, 25% to <75%, 75% to <95%, 95% to <105%, 105% to <125%, 125% to <175%, 175 to 250%, and >250% of the commanded amount.
   d. A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warm-up period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on the drug delivered) may be provided as follows, as applicable:
      i. The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point.
   e. A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an

occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps.

f. For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.
g. For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Alternate controller enabled infusion pump they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Joseph Kotarek at 301-796-2718.

Sincerely,

Kellie B. Kelm -S

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