December 13, 2019

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

Re: DEN190034
Trade/Device Name: Control-IQ Technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI
Dated: July 12, 2019
Received: July 15, 2019

Dear Michael Sarrasin:

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 Control-IQ Technology, a prescription device with the following indications for use:

> Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.
>
> Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 14 years of age and greater.
>
> Control-IQ technology is intended for single patient use and requires a prescription.
>
> Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.

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 Control-IQ Technology, and substantially equivalent devices of this generic type, into Class II under the generic name Interoperable automated glycemic controller.

FDA identifies this generic type of device as:

> **Interoperable automated glycemic controller**. An interoperable automated glycemic controller is a device intended to automatically calculate drug doses based on inputs such as glucose and other relevant physiological parameters, and to command the delivery of such drug doses from a connected infusion pump. Interoperable automated glycemic controllers are designed to reliably and securely communicate with digitally connected devices to allow drug delivery commands to be sent, received, executed, and confirmed. Interoperable automated glycemic controllers are intended to be used in conjunction with digitally connected devices for the purpose of maintaining glycemic control.

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 July 15, 2019, FDA received your De Novo requesting classification of the Control-IQ Technology. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Control-IQ 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 Control-IQ 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 inappropriate drug delivery	Clinical data demonstrating device performance Certain software validation testing User training plan Certain drug compatibility information in labeling
Risk due to poorer or different performance in pediatric populations	Clinical data demonstrating device performance in pediatric population Certain contraindications, warning statements, and precautions in labeling

Identified Risk	Mitigation Measures
Risk due to the inability of the controller to handle different pharmacokinetic/pharmacodynamic characteristics of the drugs	Clinical data demonstrating device performance Drug compatibility information in labeling User training plan Human factors testing
Risk due to lack of compatibility of connected devices	Certain validation of communication specifications, processes, and procedures with digitally connected devices Limitations on interoperable devices
Risk of connected devices having inadequate performance to allow safe use of the controller	Specifications for performance of connected devices Certain validation of communication specifications, processes, and procedures with digitally connected devices Limitations on interoperable devices
Failure to report device malfunctions or adverse events to the device manufacturer	Plans and procedures for assigning post-market responsibilities.
Risk of latent flaws in software	Robust software validation testing Certain validation of communication specifications, processes, and procedures with digitally connected devices Certain verification and validation of risk control measures
Failure to provide appropriate treatment due to loss of communication with connected devices	Certain verification and validation of risk control measures Certain validation of communication specifications, processes, and procedures with digitally connected devices
Risk due to insecure transmission of data	Certain validation of communication specifications, processes, and procedures with digitally connected devices
Failure to correctly operate the device	Human factors testing User training plan Compatible devices listed in labeling Certain warning statements and precautions in labeling
Failure to correctly determine the root cause of device malfunctions	Certain verification and validation of logging capability
Risk due to data transmission interference/electromagnetic disturbance	Certain verification and validation of electrical safety, electromagnetic compatibility, and radio frequency wireless testing

In combination with the general controls of the FD&C Act, the Interoperable automated glycemic controller is subject to the following special controls:

1. Design verification and validation must include:
    i. An appropriate, as determined by FDA, clinical implementation strategy, including data demonstrating appropriate, as determined by FDA, clinical performance of the device for its intended use, including all of its indications for use.
        A. The clinical data must be representative of the performance of the device in the intended use population and in clinically relevant use scenarios and sufficient to demonstrate appropriate, as determined by FDA, clinical performance of the device for its intended use, including all of its indications for use.
        B. For devices indicated for use with multiple therapeutic agents for the same therapeutic effect (e.g., more than one type of insulin), data demonstrating performance with each product or, alternatively, an appropriate, as determined by FDA, clinical justification for why such data are not needed.
        C. When determined to be necessary by FDA, the strategy must include postmarket data collection to confirm safe real-world use and monitor for rare adverse events.
    ii. Results obtained through a human factors study that demonstrates that an intended user can safely use the device for its intended use.
    iii. A detailed and appropriate, as determined by FDA, strategy to ensure secure and reliable means of data transmission with other intended connected devices.
    iv. Specifications that are appropriate, as determined by FDA, for connected devices that shall be eligible to provide input to (e.g., specification of glucose sensor performance) or accept commands from (e.g., specifications for drug infusion pump performance) the controller, and a detailed strategy for ensuring that connected devices meet these specifications.
    v. Specifications for devices responsible for hosting the controller, and a detailed and appropriate, as determined by FDA, strategy for ensuring that the specifications are met by the hosting devices.
    vi. Documentation demonstrating that appropriate, as determined by FDA, measures are in place (e.g., validated device design features) to ensure that safe therapy is maintained when communication with digitally connected devices is interrupted, lost, or re-established after an interruption. Validation testing results must demonstrate that critical events that occur during a loss of communications (e.g., commands, device malfunctions, occlusions, etc.) are handled and logged appropriately during and after the interruption to maintain patient safety.
    vii. A detailed plan and procedure for assigning post-market responsibilities including adverse event reporting, complaint handling, and investigations with the manufacturers of devices that are digitally connected to the controller.
2. Design verification and validation documentation 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:
    i. Risk control measures to address device system hazards;
    ii. Design decisions related to how the risk control measures impact essential performance; and
    iii. 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 appropriate, as determined by FDA, and validated interface specifications for digitally connected devices. These interface specifications shall, at a minimum, provide for the following:
    i. Secure authentication (pairing) to connected devices;
    ii. Secure, accurate, and reliable means of data transmission between the controller and connected devices;
    iii. Sharing of necessary state information between the controller and any connected devices (e.g., battery level, reservoir level, sensor use life, pump status, error conditions);
    iv. Ensuring that the controller continues to operate safely when data is received in a manner outside the bounds of the parameters specified;
    v. A detailed process and procedures for sharing the controller's interface specification with connected devices and for validating the correct implementation of that protocol; and
    vi. A mechanism for updating the controller software, including any software that is required for operation of the controller in a manner that ensures its safety and performance.
4. 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 controller must, at a minimum, include:
    i. Commands issued by the controller, and associated confirmations the controller receives from digitally connected devices;
    ii. Malfunctions of the controller and malfunctions reported to the controller by digitally connected devices (e.g., infusion pump occlusion, glucose sensor shut down);
    iii. Alarms and alerts and associated acknowledgements from the controller as well as those reported to the controller by digitally connected devices; and
    iv. Connectivity events (e.g., establishment or loss of communications).
5. The device must only receive glucose input from devices cleared under 21 CFR 862.1355 (Integrated continuous glucose monitoring system), unless FDA determines an alternate type of glucose input device is designed appropriately to allow the controller to meet the special controls contained within this section.
6. The device must only command drug delivery from devices cleared under 21 CFR 880.5730 (Alternate controller enabled infusion pump), unless FDA determines an alternate type of drug infusion pump device is designed appropriately to allow the controller to meet the special controls contained within this section.
7. An appropriate, as determined by FDA, training plan must be established for users and healthcare providers to assure the safety and performance of the device when used. This may include, but not be limited to, training on device contraindications, situations in which the device should not be used, notable differences in device functionality or features compared to similar alternative therapies, and information to help prescribers identify suitable candidate patients, as applicable.
8. The labeling required under 21 CFR 809.10(b) must include:
    i. A contraindication for use in pediatric populations except to the extent clinical performance data or other available information demonstrates that it can be safely used in pediatric populations in whole or in part.
    ii. A prominent statement identifying any populations for which use of this device has been determined to be unsafe.
    iii. A prominent statement identifying by name the therapeutic agents that are compatible with the controller, including their identity and concentration, as appropriate.

iv. The identity of those digitally connected devices with which the controller can be used, including descriptions of the specific system configurations that can be used, per the detailed strategy submitted under paragraph (1)(iii).
v. A comprehensive description of representative clinical performance in the hands of the intended user, including information specific to use in the pediatric use population, as appropriate.
vi. A comprehensive description of safety of the device, including, for example, the incidence of severe hypoglycemia, diabetic ketoacidosis, and other relevant adverse events observed in a study conducted to satisfy paragraph (1)(i).
vii. For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.
viii. For any controller with hardware components intended for multiple patient reuse, instructions for safely reprocessing the hardware components between uses.

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 interoperable automated glycemic controller 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 Parts 801 and 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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/medical-devices/device-advice-comprehensive-regulatory-assistance)

and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Joshua Balsam at 240-402-6521.

Sincerely,

Kellie B. Kelm -S

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