March 27, 2018

Dexcom, Inc.
Neeta Sharma
Vice President, Regulatory Affairs
6340 Sequence Drive
San Diego, California 92121

Re: DEN170088
Trade/Device Name: Dexcom G6 Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QBJ
Dated: December 7, 2017
Received: December 8, 2017

Dear Neeta Sharma:

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 Dexcom G6 Continuous Glucose Monitoring System, a prescription device with the following indications for use:

> The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.
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> The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G6 System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.
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> The Dexcom G6 System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G6 System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Dexcom G6 Continuous Glucose Monitoring System, and substantially equivalent devices of this generic type, into Class II under the generic name "Integrated continuous glucose monitoring system."

FDA identifies this generic type of device as: **Integrated continuous glucose monitoring system**.

> An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to 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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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 classifying the device type.

On December 8, 2017, FDA received your De Novo requesting classification of the Dexcom G6 Continuous Glucose Monitoring System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Dexcom G6 Continuous Glucose Monitoring System 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 Dexcom G6 Continuous Glucose Monitoring System 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 Risks to Health	Mitigation Measures
Clinical action based on falsely high or falsely low inaccurate glucose values or inaccurate alerts may lead to inappropriate treatment decisions.	General Controls and special controls (1), (2), (3), (4), (5), (6), and (7)
Clinical action in pediatric patients based on falsely high or falsely low inaccurate values or inaccurate alerts due to poorer or different performance in pediatric populations.	General Controls and special controls (1), (2), (3), (4), (5), (6), and (7)

Identified Risks to Health	Mitigation Measures
The inability to make appropriate treatment decisions when glucose values are unavailable due to sensor signal drop-out or loss of communication with digitally connected devices.	General Controls and special controls (1)(vii), (2), (3), (6), and (7)
Patient harm due to insecure transmission of data.	General Controls and special control (2)
Use of an iCGM as part of another digitally connected medical device system, such as an AID system, when the iCGM has inadequate analytical or clinical performance to support the intended use of the digitally connected device.	General Controls and special controls (2), (6), and (7)

In combination with the general controls of the FD&C Act, a Integrated continuous glucose monitoring system is subject to the following special controls:

(1) Design verification and validation must include the following:

(i) Robust clinical data demonstrating the accuracy of the device in the intended use population.

(ii) The clinical data must include a comparison between iCGM values, and blood glucose values in specimens collected in parallel that are measured on an FDA-accepted laboratory-based glucose measurement method that is precise and accurate, and that is traceable to a higher order (e.g., an internationally recognized reference material and/or method).

(iii) The clinical data must be obtained from a clinical study designed to fully represent the performance of the device throughout the intended use population and throughout the measuring range of the device.

(iv) Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period.

(v) Clinical study results in the adult population must meet the following performance requirements:

(A) For all iCGM measurements less than 70 mg/dL, the percentage of iCGM measurements within +/- 15 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 85%.

(B) For all iCGM measurements from 70-180 mg/dL, the percentage of iCGM measurements within +/- 15% of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 70%.

(C) For all iCGM measurements greater than 180 mg/dL, the percentage of iCGM measurements within +/- 15% of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 80%.

(D) For all iCGM measurements less than 70 mg/dL, the percentage of iCGM measurements within +/- 40 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 98%.

(E) For all iCGM measurements from 70-180 mg/dL, the percentage of iCGM measurements within +/- 40% of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 99%.

(F) For all iCGM measurements greater than180 mg/dL, the percentage of iCGM measurements within +/- 40% of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 99%.

(G) Throughout the device measuring range, the percentage of iCGM measurements within +/- 20 % of the corresponding blood glucose value must be calculated, and the lower one-sided 95% confidence bound must exceed 87%.

(H) When iCGM values are less than 70 mg/dL, no corresponding blood glucose value shall read above 180 mg/dL.

(I) When iCGM values are greater than 180 mg/dL, no corresponding blood glucose value shall read less than 70 mg/dL.

(J) There shall be no more than 1% of iCGM measurements that indicate a positive glucose rate of change greater than 1 mg/dL/min when the corresponding true negative glucose rate of change is less than -2 mg/dL/min as determined by the corresponding blood glucose measurements.

(K) There shall be no more than 1% of iCGM measurements that indicate a negative glucose rate of change less than -1 mg/dL/min when the corresponding true positive glucose rate of change is greater than 2 mg/dL/min as determined by the corresponding blood glucose measurements.

(vi) Data demonstrating similar accuracy and rate of change performance of the iCGM in the pediatric population as compared to that in the adult population, or alternatively a clinical and/or technical justification for why pediatric data are not needed, must be provided and determined by FDA to be acceptable and appropriate.

(vii) Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically

significant gaps in sensor data availability that would prevent any digitally connected devices from achieving their intended use.

(2) Design verification and validation must include a detailed strategy to ensure secure and reliable means of iCGM data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the iCGM glucose data.

(3) Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications as defined in paragraphs (1) and (2) of this section.

(4) The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications.

(5) The device must include appropriate measures to ensure that disposable sensors cannot be used beyond its claimed sensor wear period.

(6) Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose measurement accuracy.

(7) Your 809.10(b) labeling must include a separate description of the following sensor performance data observed in the clinical study performed in conformance with paragraph (1) for each intended use population, in addition to separate sensor performance data for each different iCGM insertion or use sites (e.g., abdomen, arm, buttock):

(i) A description of the accuracy in the following blood glucose concentration ranges: less than 54 mg/dL, 54-70 mg/dL, 70-180 mg/dL, 180-250 mg/dL, and greater than 250 mg/dL.

(ii) A description of the accuracy of positive and negative rate of change data.

(iii) A description of the frequency and duration of gaps in sensor data.

(iv) A description of the true, false, missed, and correct alert rates and a description of the available glucose concentration alert settings if applicable.

(v) A description of the observed duration of iCGM life for the device.

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 integrated continuous glucose monitoring system 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); 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 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 Andrea Bell-Vlasov at 240-402-4977.

Sincerely,

Courtney H. Lias -S

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