



Food and Drug Administration  
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ANDREW BALO  
SENIOR VICE PRESIDENT, REGULATORY, BIOMETRICS, & CLINICAL AFFAIRS  
DEXCOM, INC.  
6340 SEQUENCE DRIVE  
SAN DIEGO, CA 92121

Re: DEN140038  
Dexcom Share Direct Secondary Displays  
Evaluation of Automatic Class III Designation – *De Novo* Request  
Regulation Number: 21 CFR 862.1350  
Regulation Name: Continuous glucose monitor secondary display  
Regulatory Classification: Class II  
Product Code: PJT  
Dated: December 12, 2014  
Received: December 15, 2014

Dear Mr. Balo:

This letter corrects our letter sent January 23, 2015 and dated January 23, 2015.

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 Share Direct Secondary Displays, an over-the-counter device. The intended use of the Dexcom Share Direct Secondary Displays is:

The purpose of Dexcom Share Direct Secondary Displays is to notify another person, the Follower, of the patient's Dexcom G4 PLATINUM Continuous Glucose Monitoring System sensor glucose information. The Secondary Displays is intended for providing secondary notification of a continuous glucose monitoring system and does not replace real time continuous glucose monitoring (G4 PLATINUM System) or standard home blood glucose monitoring.

The Dexcom Share Direct Secondary Displays is not intended to modify or analyze data received from the continuous glucose monitor system. Nor is it intended to instruct, or to transmit information to the continuous glucose monitor system. The Dexcom Share Direct Secondary Displays is not intended to serve as a replacement for a primary display device for a continuous glucose monitoring system. The Dexcom Share Direct Secondary

Displays is not intended to receive information directly from the sensor or transmitter of a continuous glucose monitoring system.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Dexcom Share Direct Secondary Displays, and substantially equivalent devices of this generic type, into class II under the generic name, “Continuous glucose monitor secondary display”.

FDA identifies this generic type of device as: Continuous glucose monitor secondary display.

A continuous glucose monitor secondary display is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data. It must not be capable of serving as a stand-alone primary display device. The primary display device, which is not a part of the continuous glucose monitor secondary display, directly receives the glucose data (for example, it communicates directly with transmitter), from the continuous glucose meter, which is not a part of the continuous glucose monitor secondary display, and is the primary means of viewing the continuous glucose monitor data and alerting the patient to a low or high glucose value. A continuous glucose monitor secondary display can be used by caregivers of people with diabetes to monitor a person’s continuous glucose monitoring data. A device is not a continuous glucose monitor secondary device if the data from the primary display device is modified (for example predicting future glucose values) or the patient can use the secondary display in lieu of a primary display device (for example the primary display device is blinded or the primary display does not have to be near the person wearing the sensor and transmitter).

Section 513(f)(2) of 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 15, 2014, FDA received your *de novo* request for classification of the Dexcom Share Direct Secondary Displays. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Dexcom Share Direct Secondary Displays 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 the Dexcom Share Direct Secondary Displays intended for use as follows

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can be classified in class II with the establishment of special controls for this type of device. FDA believes that class II special controls identified later in this order, along with the applicable general controls, including the design controls under 21 CFR part 820, provide reasonable assurance of the safety and effectiveness of the device type.

**Table – Identified Risks to Health and Required Mitigations**

<b>Identified Risks to Health</b>	<b>Required Mitigations</b>
Incorrect glucose value reported on the secondary display or glucose value missed due to cybersecurity breach.	Special control (1)
Treatment recommendations are made based on data presented by secondary display device.	Special control (2)
Individual with diabetes becomes overly reliant on “followers” for monitoring their glucose levels.	Special control (3)

In combination with the general controls of the FD&C Act, the continuous glucose monitor secondary display is subject to the following special controls:

1. Devices being marketed must include appropriate measures to protect against unauthorized access to data and unauthorized modification of data.
2. The labeling must prominently and conspicuously display a warning that states “Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.”
3. The labeling for the device must include a limitation that states “This device is not intended to replace self-monitoring practices advised by a physician.”

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the continuous glucose monitor secondary display they intend to market prior to marketing the device and receive clearance to market from FDA.

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.

If you have any questions concerning this classification order, please contact Joshua M. Balsam at 240-402-6521.

Sincerely yours,

Courtney H Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of *In Vitro* Diagnostics and  
Radiological Health  
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