



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 25, 2019

Dexcom, Inc.
c/o Andrew Balo
Senior Vice President, Regulatory, Biometrics, & Clinical Affairs
6340 Sequence Drive
San Diego, CA 92121

Re: DEN140016
STUDIO on the Cloud Data Management Software
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 862.2120
Regulation Name: Continuous glucose monitor data management system
Regulatory Classification: Class I
Product Code: PHV
Dated: April 21, 2014
Received: April 22, 2014

Dear Mr. Balo:

This letter corrects our letter dated August 19, 2014.

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 STUDIO on the Cloud Data Management Software, a prescription home use device, which is restricted as a prescription device that must comply with 21 CFR Part 801.109. The intended use of the STUDIO on the Cloud Data Management Software is

The STUDIO on the Cloud Data Manager Software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical CGM data to support effective diabetes management. It is intended for use as an accessory to CGM devices with data interface capabilities.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class I. This order, therefore, classifies the STUDIO on the Cloud Data Management Software, and substantially equivalent devices of this generic type, into class I under the generic name, “Continuous glucose monitor data management system”.

FDA identifies this generic type of device as: Continuous glucose monitor data management system.

A continuous glucose monitor data management system is an electronic device intended to acquire, process, and correlate retrospective data from a continuous glucose monitoring device. This device is intended to be used by patients or their healthcare providers when determining therapeutic strategies. A continuous glucose monitor data management system is not a drug dose calculator and does not provide treatment recommendations.

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 April 22, 2014, FDA received your *de novo* request for classification of the STUDIO on the Cloud Data Management Software. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the STUDIO on the Cloud Data Management Software 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 STUDIO on the Cloud Data Management Software intended for use as follows

The STUDIO on the Cloud Data Manager Software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical CGM data to support effective diabetes management. It is intended for use as an accessory to CGM devices with data interface capabilities.

can be classified in class I. FDA believes that class I (general) controls, including the design controls under 21 CFR part 820 and restriction as a prescription device that must comply with 21 CFR 801.109, provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Risks and Required Mitigations

Identified Risk	Required Mitigation
Device malfunction (e.g., incorrect data analysis, etc.)	General controls, including design controls

A continuous glucose monitor data management system is subject to the general controls of the FD&C Act, including design controls. In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I

device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the continuous glucose monitor data management system they intend to market prior to marketing the device, subject to the limitations on exemptions in 21 CFR 862.9.

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); 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,

Kellie B. Kelm -S

Kellie B. Kelm, Ph.D.

Acting Director

Division of Chemistry and Toxicology Devices

OHT7: Office of In Vitro Diagnostics

and Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health