November 2, 2018

Dexcom, Inc.
Luke Olson
Senior Specialist, Regulatory Affairs
6340 Sequence Dr.
San Diego, CA 92121

Re: K182405
Trade/Device Name: Dexcom Pro Q Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QDL
Dated: August 30, 2018
Received: September 4, 2018

Dear Luke Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 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/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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Kellie B. Kelm -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182405

Device Name
Dexcom Pro Q Continuous Glucose Monitoring System

Indications for Use *(Describe)*
The Dexcom Pro Q Continuous Glucose Monitoring System (Dexcom Pro Q System) is a factory calibrated continuous glucose recording device indicated for the retrospective discovery, analysis, and interpretation of glycemic variability in persons age 2 years and older under the supervision of a healthcare professional. The Dexcom Pro Q System collects and processes data for aiding in the management of a disease or condition related to glycemic control.

Interpretation of the data recorded by the Dexcom Pro Q System results should be made only by a qualified healthcare professional based on glucose trends and several sequential readings over time. The Dexcom Pro Q System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom Pro Q System is also intended to interface with digitally connected devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K182405

5.1 SUBMITTER:

Dexcom, Inc.
6340 Sequence Dr.
San Diego, CA 92121

Contact: Luke Olson

Senior Regulatory Affairs Specialist

Phone: 858.875.5307

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Date Prepared: November 2, 2018

5.2 DEVICE NAMES AND CLASSIFICATION:

Proprietary Name	Dexcom Pro Q Continuous Glucose Monitoring System
Common Name	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QDL
Review Panel	Clinical Chemistry

5.3 PREDICATE DEVICE:

Dexcom G6 Continuous Glucose Monitoring (CGM) System

5.4 DEVICE DESCRIPTION:

The Dexcom Pro Q Continuous Glucose Monitoring System (Dexcom Pro Q System) is a continuous glucose monitor that offers an altered feature set versus the predicate Dexcom G6 CGM System.

The Dexcom Pro Q System consists of two main components: sensor/applicator delivery system, and a transmitter. The sensor is a small and flexible wire inserted into subcutaneous tissue where it converts glucose into electrical current. The transmitter is connected to the sensor and is worn on the body. It samples the electrical current produced by the sensor and converts these measurements into glucose readings using an onboard algorithm. The transmitter logs estimated glucose values every 5 minutes during the sensor wear period (up to 10 days).

5.5 INDICATIONS FOR USE:

The Dexcom Pro Q Continuous Glucose Monitoring System (Dexcom Pro Q System) is a factory calibrated continuous glucose recording device indicated for the retrospective discovery, analysis, and interpretation of glycemic variability in persons age 2 years and older under the supervision of a healthcare professional. The Dexcom Pro Q System collects and processes data for aiding in the management of a disease or condition related to glycemic control.

Interpretation of the data recorded by the Dexcom Pro Q System results should be made only by a qualified healthcare professional based on glucose trends and several sequential readings over time. The Dexcom Pro Q System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom Pro Q System is also intended to interface with digitally connected devices.

5.6 COMPARISON WITH THE PREDICATE DEVICE:

Device	Dexcom Pro Q System (K182405)	Dexcom G6 CGM System (DEN170088)
Trade Name	Dexcom Pro Q Continuous Glucose Monitoring System	Dexcom G6 Continuous Glucose Monitoring System
Manufacturer	Dexcom, Inc.	Dexcom, Inc.
Intended Use	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.	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.
Indications for Use	The Dexcom Pro Q Continuous Glucose Monitoring System (Dexcom Pro Q System) is a factory calibrated continuous glucose recording device indicated for the retrospective discovery, analysis, and interpretation of glycemic variability in persons age 2 years and older under the supervision of a healthcare professional. The Dexcom Pro Q System collects and processes data for aiding in the management of a disease or condition related to glycemic control. Interpretation of the data recorded by the Dexcom Pro Q System results should be made only by a qualified healthcare professional based on glucose trends and several sequential readings over time. The Dexcom Pro Q System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom Pro Q	The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 CGM System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older. 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. The Dexcom G6 System is also intended to autonomously communicate with digitally connected devices, including

Device	Dexcom Pro Q System (K182405)	Dexcom G6 CGM System (DEN170088)
	System is also intended to interface with digitally connected devices.	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.
Clinical application	Management of a disease or condition related to glycemic control	Management of a disease or condition related to glycemic control
Clinical setting/sites of use	Home use (sensor insertion and interpretation of retrospective glucose data occurs in clinic with a healthcare professional)	Home use
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction
Data Presented	**Estimated Glucose Value (EGV):** The EGV is the nominal glucose value presented to the user and healthcare professional after the sensor session. **Historical Glucose Data:** The glucose data collected throughout the entire wear-period is presented to the user and healthcare professional after the sensor session.	**Estimated Glucose Value (EGV):** The EGV is the nominal glucose value presented to the user in real-time. Based off the glucose rate of change, users are shown their real-time glucose trend with a corresponding arrow. **Historical Glucose Data:** Users can view their previous three, six, twelve, or twenty-four hours of glucose data.
Features	**Analysis with a healthcare professional:** Healthcare professionals can view the user's glucose data collected across the entire sensor session to aid in the management of a disease or condition related to glycemic control.	**Connect to Dexcom Share:** Users can share their glucose data to the cloud, which communicates with Clarity, and allows both users and healthcare professionals to view glucose data.
Compatibility with intended environments	Compatible authorized data extraction device.	Compatible with iPhone 5S through iPhone X, Samsung Note 5, Note 8, Galaxy S6-S9, J3, Google Pixel, LG G5-G6 Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above. Compatible with authorized interoperable devices, including automated insulin delivery devices

5.7 Summary of Performance Testing

The Dexcom Pro Q System was verified and validated according to Dexcom's internal design control process and in accordance with special controls for integrated continuous glucose monitors. This testing demonstrated that the system performed according to its specifications and that the technological and performance criteria are comparable to the predicate device.

5.8 Conclusions Drawn from Performance Testing

The Dexcom Pro Q System is substantially equivalent to the Dexcom G6 CGM System as they are identical with regard to intended use and there are no differences in technological characteristics that raise different questions of safety and effectiveness. The Dexcom Pro Q System provides healthcare professionals with retrospective glucose data to assist in the development of individualized care plans.