October 7, 2019

Dexcom, Inc.
Jacob Nardone
Staff Regulatory Affairs Specialist
6340 Sequence Dr.
San Diego, CA 92121

Re: K191833
Trade/Device Name: Dexcom G6 Pro Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QII
Dated: July 8, 2019
Received: July 9, 2019

Dear Jacob Nardone:

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/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 Act); 21 CFR 1000-1050.


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

Sincerely,

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

Enclosure
Indications for Use

The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time.

The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional.

The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.

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

- [x] 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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
5 510(k) SUMMARY

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

The assigned 510(k) number is: K191833

5.1 SUBMITTER:

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

Contact: Jacob Nardone
       Staff Regulatory Affairs Specialist
Phone: 858.203.6337
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Phone: 858.875.5326
Fax: 858.332.0204
Email: hdrake@dexcom.com

Date Prepared: October 7th, 2019

5.2 DEVICE NAMES AND CLASSIFICATION:

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Dexcom G6 Pro Continuous Glucose Monitoring System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Integrated Continuous Glucose Monitoring System, Factory Calibrated</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
</tr>
<tr>
<td>Classification Regulation</td>
<td>21 CFR 862.1355</td>
</tr>
<tr>
<td>Product Code</td>
<td>QII</td>
</tr>
<tr>
<td>Review Panel</td>
<td>Clinical Chemistry</td>
</tr>
</tbody>
</table>
5.3 **Predicate Device:**

Dexcom G6 Continuous Glucose Monitoring System (K191450)

5.4 **Device Description:**

5.4.1 **Dexcom G6 Pro Continuous Glucose Monitoring System**

The Dexcom G6 Pro Continuous Glucose Monitoring (G6 Pro) System is a continuous glucose monitor that offers an introduction to CGM for users who would benefit from the supervision of their qualified Healthcare Professional (HCP) during early or initial use of CGM. The predicate of the Dexcom G6 Pro CGM System is the Dexcom G6 CGM System. G6 Pro consists of three main components: a sensor/applicator delivery system, a transmitter, and a mobile application (app). The sensor/applicator is identical to the sensor/applicator used in the G6 CGM System (K191450). The sensor is a small and flexible wire inserted into subcutaneous tissue where it converts glucose into electrical current.

The G6 Pro 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 G6 Pro Transmitter’s firmware includes an auto-start feature which enables the transmitter to start a session immediately upon attachment of the transmitter to the on-body wearable. The G6 Pro Transmitter can be used as a retrospective CGM data logger and it can also send real-time estimated glucose values to the G6 Mobile Application. The HCP selects which type of CGM session the patient receives (retrospective vs. real-time). The G6 Pro Transmitter Firmware supports a single-use 10-day sensor session per transmitter.

The G6 App displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 24 hours) from the transmitter.
5.5  **INDICATIONS FOR USE:**

5.5.1  **Dexcom G6 Pro Continuous Glucose Monitoring System**

The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time.

The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional.

The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.
5.6 COMPARISON WITH THE PREDICATE DEVICE:

5.6.1 Dexcom G6 Pro Continuous Glucose Monitoring System (subject device) to Dexcom G6 Continuous Glucose Monitoring System (K191450)

<table>
<thead>
<tr>
<th>Device</th>
<th>Dexcom G6 Continuous Glucose Monitoring System (K191450)</th>
<th>Dexcom G6 Pro Continuous Glucose Monitoring System (subject device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name</td>
<td>Dexcom G6 Continuous Glucose Monitoring System</td>
<td>Dexcom G6 Pro Continuous Glucose Monitoring System</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Dexcom, Inc.</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The System is an integrated continuous glucose monitoring system (iCGM) intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. The System is designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and is 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.</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing</td>
</tr>
<tr>
<td>Device</td>
<td>Dexcom G6 Continuous Glucose Monitoring System (K191450)</td>
<td>Dexcom G6 Pro Continuous Glucose Monitoring System (subject device)</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td>glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional. The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.</td>
</tr>
<tr>
<td>Clinical application</td>
<td>Management of diabetes mellitus</td>
<td>Management of diabetes mellitus or assessing glycemic variability</td>
</tr>
<tr>
<td>Clinical setting/sites of use</td>
<td>Home use</td>
<td>Home use (sensor insertion, transmitter attachment and retrospective glucose data download occurs in a clinic with the supervision of a healthcare professional)</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction</td>
<td>Same</td>
</tr>
</tbody>
</table>
| Data Presented | **Estimated Glucose Value (EGV):** The EGV is the nominal glucose value presented to the user.  
**Glucose Trend:** Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow.  
**Historical Glucose Data:** Users can view their previous three, six, twelve, or twenty-four hours of glucose data. | Same |
<p>| Features | <strong>Connect to Dexcom Share:</strong> Users can share their glucose data with followers. | Same |</p>
<table>
<thead>
<tr>
<th>Device</th>
<th>Dexcom G6 Continuous Glucose Monitoring System (K191450)</th>
<th>Dexcom G6 Pro Continuous Glucose Monitoring System (subject device)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Human Factors</strong></td>
<td>Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Transmitter Use Life</strong></td>
<td>Reusable (90 days)</td>
<td>Single-Use (10-day)</td>
</tr>
<tr>
<td><strong>Supported CGM Data Methods</strong></td>
<td>Real-Time</td>
<td>Real-Time and Retrospective</td>
</tr>
<tr>
<td><strong>Factory Calibration</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Optional Calibration</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Compatibility with intended environments</strong></td>
<td>Android OS version 7.0.0 - 9.0.0 iOS 11.0.0 - 12.1.4</td>
<td>Same</td>
</tr>
</tbody>
</table>
5.7 **TECHNOLOGICAL CHARACTERISTICS**

The proposed Dexcom G6 Pro Continuous Glucose Monitoring System shares the same technological characteristics as the predicate Dexcom G6 Continuous Glucose Monitoring System (K191450). Both Systems are used to measure glucose values via an amperometric measurement of current proportional to glucose concentration in interstitial fluid via a glucose oxidase chemical reaction.

5.8 **SUMMARY OF PERFORMANCE TESTING**

The proposed Dexcom G6 Pro Continuous Glucose Monitoring 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.

5.9 **CONCLUSIONS**

The Dexcom G6 Pro Continuous Glucose Monitoring System is a professional product designed to assist patients in a home environment better manage diabetes mellitus while under HCP supervision. The Dexcom G6 Pro Continuous Glucose Monitoring System may also be used as a retrospective glucose recording device that allows HCPs to assess glycemic variability of patients in a home environment. The Dexcom G6 Pro Continuous Glucose Monitoring System is substantially equivalent to the Dexcom G6 Continuous Glucose Monitoring System as they are identical with regard to intended use and there are no differences in indications, technological characteristics or performance that raise new questions of safety and effectiveness.