June 28, 2019

Dexcom, Inc.
Emily Chung
Senior Specialist, Regulatory Affairs
6310 Sequence Dr.
San Diego, CA 92121

Re: K191450
Trade/Device Name: Dexcom G6 Glucose Program Continuous Glucose Monitoring System
Dexcom G6 Glucose Program Continuous Glucose Monitoring System
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: QBJ, QDK, QDL
Dated: May 30, 2019
Received: May 31, 2019

Dear Emily Chung:

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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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, 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

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)*
K191450

Device Name
Dexcom G6 Continuous Glucose Monitoring System

Indications for Use *(Describe)*
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.

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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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."

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)*
K191450

Device Name
Dexcom G6 Glucose Program Continuous Glucose Monitoring System

Indications for Use *(Describe)*
The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 2 years and older.

The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions for persons with diabetes who are not at significant risk of severe hypoglycemia. Interpretation of the Dexcom Glucose Program System results should be based on the glucose trends and several sequential readings over time. The Dexcom Glucose Program System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating long-term therapy adjustments.

The Dexcom Glucose Program System is also intended to autonomously communicate with digitally connected devices. The Dexcom Glucose Program System can be used alone or in conjunction with these digitally connected devices or services for the purpose of managing diabetes.

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.

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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)*
K191450

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.

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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

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SECTION 6 510(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: K191450

6.1 SUBMITTER:

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

Contact: Emily Chung
Senior Specialist, Regulatory Affairs
Phone: 858.529.4737
Fax: 858.332.0204
Email: echung@dexcom.com

Secondary
Contact: Holly Drake
Senior Manager, Regulatory Affairs
Phone: 858.875.5326
Fax: 858.332.0204
Email: hdrake@dexcom.com

Date Prepared: May 30, 2019

6.2 DEVICE NAMES AND CLASSIFICATION:

Predicate Device	
Proprietary Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System
Common Name	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QBJ

Review Panel	Clinical Chemistry
Other Devices	
Proprietary Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring System
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QDK
Proprietary Name	Dexcom Pro Q Continuous Glucose Monitoring System
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QDL

6.3 PREDICATE DEVICE:

Dexcom G6 Continuous Glucose Monitoring (CGM) System (K183206)

Dexcom G6 Glucose Program Continuous Glucose Monitoring System (K182041)

Dexcom Pro Q Continuous Glucose Monitoring System (K182405)

6.4 DEVICE DESCRIPTION:

6.4.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) consists of three main components: a sensor, a Bluetooth Low Energy (BLE) transmitter, and a BLE enabled display device (receiver and/or mobile app). 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 sends glucose data to the receiver and/or mobile app which displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 12 hours) from the transmitter. The G6 System does not require calibrations using SMBG, and the sensor life has an expected wear time of up to 10 days. The receiver and/or mobile app displays the current glucose reading and glucose trends to the user. It alerts the user when glucose levels are outside of a target zone and when other important system conditions occur.

6.4.2 Dexcom G6 Glucose Program Continuous Glucose Monitoring System

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

The Dexcom Glucose Program System consists of three main components: a sensor/applicator delivery system, a transmitter, and a mobile application (app). 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 sends glucose data to the app. The app displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 12 hours) from the transmitter. The app alerts users of important system conditions, when it enters an error state, or when it requires the user to enter information. The app also supports connectivity to Dexcom Share and Follow (DEN140016).

6.4.3 Dexcom Pro Q Continuous Glucose Monitoring System

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 Dexcom G6 CGM System.

The Dexcom Pro Q System consists of two main components: a 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).

The proposed Dexcom G6 System, Dexcom G6 Glucose Program System, and Dexcom Pro Q System are based on the same physical principles and fundamental design as the predicate for each respective System but includes an alternative adhesive patch. The adhesive patch adheres the transmitter wearable to the user's body. The Dexcom G6 System, Dexcom G6 Glucose Program System, and the Dexcom Pro Q System are designed to function as intended with either the proposed or current adhesive patch. The proposed adhesive patch has the same form, fit, and function as the commercial adhesive patch and, from the users' perspective, functions identically.

6.5 INDICATIONS FOR USE

6.5.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

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.

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 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.

6.5.2 Dexcom G6 Glucose Program Continuous Glucose Monitoring System

The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.

The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions for persons with diabetes who are not at significant risk of severe hypoglycemia. Interpretation of the Dexcom Glucose Program System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom Glucose Program System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating long-term therapy adjustments.

The Dexcom Glucose Program System is also intended to autonomously communicate with digitally connected devices. The Dexcom Glucose Program System can be used alone or in conjunction with these digitally connected devices or services for the purpose of managing diabetes.

6.5.3 Dexcom Pro Q Continuous Glucose Monitoring System

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.

6.6 COMPARISON WITH THE PREDICATE DEVICE:

6.6.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

Device	**Dexcom G6 CGM System (subject device, K191450)**	**Dexcom G6 CGM System (K183206)**
Trade Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System	Dexcom G6 Continuous Glucose Monitoring (CGM) 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 G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated	The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated

Device	Dexcom G6 CGM System (subject device, K191450)	Dexcom G6 CGM System (K183206)
	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 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.	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 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 diabetes mellitus	Management of diabetes mellitus
Clinical setting/sites of use	Home use	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. **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.	**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.
Features	**Connect to Dexcom Share:** Users can share their glucose data with up to five followers.	**Connect to Dexcom Share:** Users can share their glucose data with up to five followers.

Device	Dexcom G6 CGM System (subject device, K191450)	Dexcom G6 CGM System (K183206)
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.
Compatibility with intended environments	iPhone 4S- iPhone X, Google Pixel, Google Pixel 2, Samsung Galaxy Note 5, Samsung Galaxy Note 8, Samsung Galaxy S6, Samsung Galaxy S6 Edge, Samsung Galaxy S7, Samsung Galaxy S7 Edge, Samsung Galaxy S8, Samsung Galaxy S8 Plus, Samsung Galaxy S9, Samsung Galaxy S9+, Samsung Galaxy J3 [SM-J327 models only, including J3 Eclipse, J3 Emerge, J3 Prime, Express Prime 2, Amp Prime 2], LG G5, LG G6 Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above.	iPhone 4S- iPhone X, Google Pixel, Google Pixel 2, Samsung Galaxy Note 5, Samsung Galaxy Note 8, Samsung Galaxy S6, Samsung Galaxy S6 Edge, Samsung Galaxy S7, Samsung Galaxy S7 Edge, Samsung Galaxy S8, Samsung Galaxy S8 Plus, Samsung Galaxy S9, Samsung Galaxy S9+, Samsung Galaxy J3 [SM-J327 models only, including J3 Eclipse, J3 Emerge, J3 Prime, Express Prime 2, Amp Prime 2], LG G5, LG G6 Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above.
Adhesive Patch	MA-91 patch	Dermamed patch

6.6.2 Dexcom G6 Glucose Program Continuous Glucose Monitoring System

Device	Dexcom G6 Glucose Program System (subject device, K191450)	Dexcom G6 Glucose Program System (K182041)
Trade Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) 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	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

Device	Dexcom G6 Glucose Program System (subject device, K191450)	Dexcom G6 Glucose Program System (K182041)
	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.	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 G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older. The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions for persons with diabetes who are not at significant risk of severe hypoglycemia. Interpretation of the Dexcom Glucose Program System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom Glucose Program System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating long-term therapy adjustments. The Dexcom Glucose Program System is also intended to autonomously communicate with digitally connected devices. The Dexcom Glucose Program System can be used alone or in conjunction with these digitally connected devices or services for the purpose of managing diabetes.	The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older. The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions for persons with diabetes who are not at significant risk of severe hypoglycemia. Interpretation of the Dexcom Glucose Program System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom Glucose Program System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating long-term therapy adjustments. The Dexcom Glucose Program System is also intended to autonomously communicate with digitally connected devices. The Dexcom Glucose Program System can be used alone or in conjunction with these digitally connected devices or services for the purpose of managing diabetes.
Clinical application	Management of diabetes mellitus	Management of diabetes mellitus
Clinical setting/sites of use	Home use	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

Device	Dexcom G6 Glucose Program System (subject device, K191450)	Dexcom G6 Glucose Program System (K182041)
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 six, or twelve hours of glucose data on a graph with high/low glucose thresholds. **Time in Range:** Users can view the percent of time they spend in their target glucose range based on their configured high/low glucose thresholds.	**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 six, or twelve hours of glucose data on a graph with high/low glucose thresholds. **Time in Range:** Users can view the percent of time they spend in their target glucose range based on their configured high/low glucose thresholds.
Features	**Connect to Dexcom Share:** Users can share their glucose data with up to three followers. **Chat with Wellness Coach:** Users can chat with a third-party wellness coach for encouragement, education, and motivation regarding their diabetes management.	**Connect to Dexcom Share:** Users can share their glucose data with up to three followers. **Chat with Wellness Coach:** Users can chat with a third-party wellness coach for encouragement, education, and motivation regarding their diabetes management.
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.
Compatibility with intended environments	Compatible with the Samsung J3 Compatible with Android OS version 7.0 and above	Compatible with the Samsung J3 Compatible with Android OS version 7.0 and above
Adhesive Patch	MA-91 patch	Dermamed patch

6.6.3 Dexcom Pro Q Continuous Glucose Monitoring System

Device	Dexcom Pro Q System (subject device, K191450)	Dexcom Pro Q System (K182405)
Trade Name	Dexcom Pro Q Continuous Glucose Monitoring System	Dexcom Pro Q 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 System is also intended to interface with digitally connected devices.	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.
Clinical application	Management of a disease or condition related to glycemic control	Management of a disease or condition related to glycemic control

Device	Dexcom Pro Q System (subject device, K191450)	Dexcom Pro Q System (K182405)
Clinical setting/sites of use	Home use (sensor insertion and interpretation of retrospective glucose data occurs in clinic with a healthcare professional)	Home use (sensor insertion and interpretation of retrospective glucose data occurs in clinic with a healthcare professional)
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 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.
Features	**Analysis with a healthcare professional:** Healthcare professionals can view the user's glucose data collected across the entire sensor session l to aid in the management of a disease or condition related to glycemic control.	**Analysis with a healthcare professional:** Healthcare professionals can view the user's glucose data collected across the entire sensor session l to aid in the management of a disease or condition related to glycemic control.
Compatibility with intended environments	Compatible authorized extraction device.	Compatible authorized extraction device.
Adhesive Patch	MA-91 patch	Dermamed patch

6.7 TECHNOLOGICAL CHARACTERISTICS

The proposed Dexcom G6 System, Dexcom G6 Glucose Program System, and Dexcom Pro Q System are used to measure glucose values via amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction. The proposed Dexcom G6 System, Dexcom G6 Glucose Program System, and Dexcom Pro Q System share the same technological characteristics as their respective predicates (K183206, K182041, K182405).

6.8 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom G6 System, Dexcom G6 Glucose Program System, and Dexcom Pro Q System were 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 proposed systems performed according to their respective specifications; and the proposed systems have met their respective technological and performance criteria which have not changed from the predicate devices.

6.9 CONCLUSIONS

The proposed Dexcom G6 System, Dexcom G6 Glucose Program System, and Dexcom Pro Q System are substantially equivalent to their respective predicates as they are identical with regard to intended use and indications for use; and there are no differences in technological characteristics that raise different questions of safety and effectiveness.