July 29, 2022

Dexcom, Inc.
Rachel Ellena
Senior Specialist, Regulatory Affairs
6340 Sequence Dr.
San Diego, California 92121

Re: K221259
Trade/Device Name: Dexcom G6 Continuous Glucose Monitoring (CGM) System
Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System
Dexcom G6 Professional Continuous Glucose Monitoring (CGM) System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QBJ, QDK, QII
Dated: April 29, 2022
Received: May 2, 2022

Dear Rachel Ellena:

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221259

Device Name
Dexcom G6 Professional Continuous Glucose Monitoring (CGM) System

Indications for Use *(Describe)*

The Dexcom G6 Professional 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)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221259

Device Name
Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) 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 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221259

Device Name
Dexcom G6 Continuous Glucose Monitoring (CGM) 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)

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7. 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: K221259

7.1. Submitter

Dexcom, Inc.
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San Diego, CA 92121
Contact: Rachel Ellena
Position/Title: Senior Specialist, Regulatory Affairs
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Email: linda.wang@dexcom.com

Date Prepared: July 26, 2022

7.2. Device Names and Classification

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
Proprietary Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QDK
Review Panel	Clinical Chemistry
Proprietary Name	Dexcom G6 Professional Continuous Glucose Monitoring (CGM) System
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QII
Review Panel	Clinical Chemistry

7.3. Predicate Device

Dexcom G6 Continuous Glucose Monitoring (CGM) System (K201328, cleared July 15, 2021)

Dexcom G6 Glucose Program CGM System (K203089, cleared August 17, 2021)

Dexcom G6 Professional CGM System (K191833, cleared October 7, 2019)

7.4. Device Description

The proposed Dexcom G6 CGM System, Dexcom G6 Glucose Program CGM System, and Dexcom G6 Professional CGM System are based on the same physical principles and fundamental design as the predicate for each respective system but includes a modified adhesive patch. The adhesive patch adheres the transmitter holder to the user's body. The Dexcom G6 CGM System, Dexcom G6 Glucose Program CGM System, and the Dexcom G6 Professional CGM 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.

7.4.1. Dexcom G6 CGM System

The Dexcom G6 Continuous Glucose Monitoring System is an interoperable connected device that measures and displays glucose values for patients with diabetes. The G6 CGM System consists of three main components: a sensor/applicator, a Bluetooth Low Energy (BLE) transmitter, and a BLE enabled display device (receiver and/or mobile application). The sensor is a small and flexible wire, which is inserted by the applicator into subcutaneous tissue where it converts glucose into electrical current. The sensor has an expected wear time of up to 10 days. The transmitter is connected to the sensor and is worn on the body. The transmitter samples the electrical current produced by the sensor and converts these measurements into estimated glucose values (EGV) 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. The receiver and/or mobile app also alerts the user when glucose levels are outside of a target zone and when other important system conditions occur. The G6 CGM System is designed to be used alone or in conjunction with digitally connected devices. The G6 CGM System can communicate Estimated Glucose Values (EGV) and other information wirelessly and securely to and from these digitally connected devices.

7.4.2. Dexcom G6 Glucose Program CGM System

The Dexcom G6 Glucose Program Continuous Glucose Monitoring System measures and displays glucose values and trends for patients with diabetes who are not at significant risk of severe hypoglycemia. The system is factory calibrated and provides continuous glucose readings at five-minute intervals for up to ten days of use. The system consists of a sensor/applicator, a Bluetooth Low Energy (BLE) transmitter, and a mobile CGM software module (app module) that is embedded within a third-party program provider's mobile app (host app).

The sensor is a small and flexible wire, which is inserted by the applicator into subcutaneous tissue where it converts glucose into electrical current. The transmitter is connected to the sensor and is worn on the body. The transmitter samples the electrical current produced by the sensor and converts these measurements into estimated glucose values (EGV) using an

onboard algorithm. The transmitter sends glucose data to the app module, which displays the current glucose reading (updated every 5 minutes) and glucose trends. The app module does not include any glucose related alarm or alerts but will alert the user when important system conditions occur.

7.4.3. Dexcom G6 Professional CGM System

The Dexcom G6 Professional CGM 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 G6 Professional CGM 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 G6 Professional CGM System 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 Professional CGM System 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 Professional CGM System 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 elects which type of CGM session the patient receives (retrospective vs. real-time). The G6 Professional CGM System transmitter firmware supports a single-use 10-day sensor session per transmitter. The G6 Mobile Application displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 24 hours) from the transmitter.

7.5. Indications for Use

7.5.1. Dexcom G6 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.

7.5.2. Dexcom G6 Glucose Program CGM 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 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.

7.5.3. Dexcom G6 Professional CGM System

The Dexcom G6 Professional 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.

7.6. Comparison with the Predicate Device

7.6.1. Dexcom G6 CGM System

Device	Predicate Device (K201328)	Subject Device
Trade Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System	Same
Manufacturer	Dexcom, Inc.	Same
General Device Characteristics		
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	Same

Device	Predicate Device (K201328)	Subject Device
	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 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.	Same
Clinical Application	Management of diabetes mellitus	Same
Clinical Setting/Sites of Use	Home Use	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
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
Glucose Value Estimation Algorithm	Joint Probability Algorithm	Same
Factory Calibration	Yes	Same
Optional Calibration	Yes	Same
Features	Connect to Dexcom Share: Users can share their glucose data with followers. Partner Web APIs: Users can share their glucose data with client software.	Same
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same

Device	Predicate Device (K201328)	Subject Device
Adhesive Patch	Dermamed patch MA-91/MA-128 patch	**Substantially Equivalent** with no adverse impact on safety or effectiveness. The proposed Dexcom G6 CGM System uses a medical grade MA-173 adhesive patch

7.6.2. Dexcom G6 Glucose Program CGM System

Device	Predicate Device (K203089)	Subject Device
Trade Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System	Same
Manufacturer	Dexcom, Inc.	Same
General Device Characteristics		
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.	Same
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.	Same
Clinical Application	Management of diabetes mellitus	Same

Device	Predicate Device (K203089)	Subject Device
Clinical Setting/Sites of Use	Home Use	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
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. 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.	Same
Glucose Value Estimation Algorithm	Joint Probability Algorithm	Same
Factory Calibration	Yes	Same
Optional Calibration	No	Same
Features	Chat feature can be accessed through the host app	Same
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same
Adhesive Patch	Dermamed patch MA-91/MA-128 patch	**Substantially Equivalent** with no adverse impact on safety or effectiveness. The proposed Dexcom G6 Glucose Program CGM System uses a medical grade MA-173 adhesive patch

7.6.3. Dexcom G6 Professional CGM System

Device	Predicate Device (K191833)	Subject Device
Trade Name	Dexcom G6 Professional Continuous Glucose Monitoring (CGM) System	Same
Manufacturer	Dexcom, Inc.	Same
General Device Characteristics		
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	Same

Device	Predicate Device (K191833)	Subject Device
	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 Professional 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.	Same
Clinical Application	Management of diabetes mellitus or assessing glycemic control in other conditions	Same
Clinical Setting/Sites of Use	Home use (sensor insertion, transmitter attachment and retrospective glucose data download occurs in a clinic with a healthcare professional)	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
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
Glucose Value Estimation Algorithm	Joint Probability Algorithm	Same
Factory Calibration	Yes	Same
Optional Calibration	No	Same
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features.	Same

Device	Predicate Device (K191833)	Subject Device
	Color-coded graphics.	
Compatibility with Intended Environments	Android OS and Apple iOS	Same
Adhesive Patch	Dermamed patch MA-91/MA-128 patch	**Substantially Equivalent** with no adverse impact on safety or effectiveness. The proposed Dexcom G6 Professional CGM System uses a medical grade MA-173 adhesive patch

7.7. Technological Characteristics

The proposed Dexcom G6 CGM System, Dexcom G6 Glucose Program CGM System, and Dexcom G6 Professional CGM 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 CGM System, Dexcom G6 Glucose Program CGM System, and Dexcom G6 Professional CGM System share the same technological characteristics as their respective predicates (K201328, K203089, K191833).

7.8. Summary of Performance Testing

The proposed Dexcom G6 CGM System, Dexcom G6 Glucose Program CGM System, and Dexcom G6 Professional CGM 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 technological and performance criteria which have not changed from the predicate devices.

7.9. Conclusions

The proposed Dexcom G6 CGM System, Dexcom G6 Glucose Program CGM System, and Dexcom G6 Professional CGM 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.