510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k183206

B. Purpose for Submission:

Modification to the CGM Transmitter of the predicate device

C. Manufacturer and Instrument Name:

Dexcom, Inc., Dexcom G6 Continuous Glucose Monitoring System

D. Type of Test or Tests Performed:

Quantitative, amperometric assay (Glucose Oxidase)

E. System Descriptions:

1. Device Description:

The Dexcom G6 Continuous Glucose Monitoring System is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose readings which are updated every 5 minutes providing glucose levels, trends, and alerts. The System consists of three main components: a sensor, a Bluetooth Low Energy (BLE) transmitter and a BLE enabled display device (receiver and/or mobile application). The user can view glucose data on the receiver or on the G6 CGM App (i.e., a mobile medical application) running on a compatible mobile device, or on both simultaneously.

The system provides alerts and alarms which warn the user of low or impending low and high or impending high glucose levels. The user may determine their treatment based on the glucose values provided by the system.

G6 CGM SENSOR

The sensor component is a sterile device that consists of the sensor applicator, plastic base ("transmitter holder"), and sensor probe. The applicator is a single use, disposable unit that contains an introducer needle holding the sensor probe. The applicator deploys the needle and inserts the sensor under the skin. The needle is retracted back into the applicator after insertion. The sensor probe continuously measures glucose concentration in interstitial fluid and can be worn for up to 10 days.

The sensor may be worn in the abdomen for adults, and both the abdomen and buttock for children ages 2-17 years old. The sensor comes with a calibration code that the user enters into the system upon initializing a new sensor. Once the code is applied, the user does not need to calibrate the system throughout the entirety of the sensor lifetime, which is 10 days. However, the user has the option to manually calibrate the system using self-measurements from a blood glucose meter in addition to entering the calibration code. Alternatively, if the user chooses not to enter the calibration code, he or she must manually calibrate the sensor by entering two fingerstick blood glucose values during start up and every 24 hours thereafter.

G6 CGM TRANSMITTER

The G6 CGM Transmitter is a miniature radio transmitter that incorporates data processing functionality. The transmitter contains a Bluetooth radio transceiver for communication with a compatible display device (i.e., receiver and/or smart device). The transmitter attaches to the sensor and can be re-used for multiple sensing sessions up to three months.

G6 CGM RECEIVER

The G6 CGM Receiver is small hand-held device that wirelessly receives glucose information from the transmitter every five minutes and includes a touchscreen display. The 5 receiver 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.

DEXCOM G6 System MOBILE APP

The G6 CGM App for iOS and G6 CGM App for Android provides an alternative display device to the receiver for users with a compatible, BLE-enabled smart device and behaves similarly to the receiver. The G6 CGM App is compatible with certain iOS, Android and Smart Device watches. A link to a list of compatible devices is included in the instructions for use.

The Dexcom G6 System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from interoperable electronic interfaces; including compatible AID systems. The G6 CGM system is designed to communicate with interoperable devices in several ways, such as described below:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol.
- The app communicates to another app on a single mobile platform.
- The app communicates through the cloud to another software device.

2. Principles of Operation:

   The Dexcom G6 System detects glucose levels from the fluid just beneath the skin (interstitial fluid). The sensor probe continuously measures glucose concentration in the interstitial fluid via an enzymatic electrochemical reaction using glucose oxidase. The enzyme, glucose oxidase, catalyzes the oxidation of glucose and produces hydrogen peroxide. The production of hydrogen peroxide generates an electrical current that is proportionate to the interstitial glucose concentration. The transmitter converts the signal using an algorithm to a glucose value read in mg/dL, which is then transmitted to the receiver for the user to see and use accordingly.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X____ or No _____

4. Specimen Identification:

   Not applicable.

5. Specimen Sampling and Handling:

   Not applicable.

6. Calibration:

   Though the Dexcom G6 System does not require user calibration, users of the Dexcom G6 System have the option to calibrate the device manually (e.g., in situations where users do not have to use the calibration code). An evaluation of calibration stability in DEN170088 demonstrated that the system could be calibrated manually without impacting system performance.

7. Quality Control:

   Not applicable.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for

this line of product types:

Yes___X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.1355

2. Classification:

   Class II

3 Product code:

   QBJ

4. Panel:

   Chemistry (75)

G. Intended Use:

1. Indication(s) 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.

2. Special Conditions for Use Statement(s):
   - This device is for prescription use only.
   - Remove the Dexcom G6 sensor, transmitter, and receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The magnetic fields and heat could damage the components of

the Dexcom G6 System, which may cause it to display inaccurate blood glucose readings or may prevent alerts.
- This device is not intended for pregnant women, people on dialysis, or critically ill patients.
- Although standard dosing of acetaminophen (1000 mg per every 6 hours) does not appear to cause significant bias, higher supra-therapeutic levels of acetaminophen have shown significant positive bias.
- Users should adhere to the instructions for sensor insertion site; Adult users should only use the abdomen and pediatric users should only use the buttock or abdomen. Sensor performance has not been evaluated in other insertion sites and may differ from expected iCGM performance.
- Change your insertion site so it is at least 3 inches from the previous insertion site. Using the same site too often may cause irritation or scarring.
- Do not insert your sensor over irritated skin, tattoos, near waistband, bones, or scarring and near places that are easily bumped, pushed or laid on while sleeping.
- Store your sensors only between 36° F and 86° F. Do not store sensors in the freezer.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   G6 Continuous Glucose Monitoring System (DEN170088)

2. Comparison with Predicate Device:

   This submission is for modifications to the transmitter of the predicate Dexcom G6 Continuous Glucose Monitoring System. The candidate transmitter has the same overall form, fit, and function as the predicate transmitter. The sensor, algorithm, receiver, and mobile App (iOS and Android) remain unchanged.

Similarities		
Item	Candidate Device: Dexcom G6 Continuous Glucose Monitoring System	Predicate Device: Dexcom G6 Continuous Glucose Monitoring System (DEN170088)
Intended use	Real time, continuous glucose monitoring device for the management of diabetes in persons age 2 years and older. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions.	Same
Detection Method	Amperometric electrochemical	Same
Enzyme	Glucose oxidase	Same

Similarities		
Item	Candidate Device: Dexcom G6 Continuous Glucose Monitoring System	Predicate Device: Dexcom G6 Continuous Glucose Monitoring System (DEN170088)
Sample Type	Interstitial fluid	Same
Test Range	40-400 mg/dL	Same
Glucose reading update interval	Autonomously every 5 minutes	Same
Anatomical sensor wear locations	Abdomen (age 2+ years) or upper buttocks (age 2-17 years)	Same
Sensor dimensions	45º insertion angle, 8mm depth, 0.2mm diameter	Same
Sensor calibration	Factory calibrated, with optional user calibration	Same
Sensor warm up time	2 hours	Same
Sensor life	Up to 10 days (automatic sensor shutoff)	Same
Operational conditions	Ambient Temperature: 50ºF – 107.6ºF Humidity: 10%-95% RH Altitude: -1300 feet to 13,800 feet	Same
Wireless communications protocol	Bluetooth Core Specification v4.0	Same
Communications range	20 feet	Same
Transmitter dimensions	Length: 1.8 inches Width: 1.2 inches Thickness: 0.6 inches	Same
Transmitter life	Up to 3 months	Same

Differences		
Item	Candidate Device: Dexcom G6 Continuous Glucose Monitoring System	Predicate Device: Dexcom G6 Continuous Glucose Monitoring System (DEN170088)
Transmitter exterior design	Hardware is encapsulated by two plastic (polyetherimide) shells, which are ultrasonically welded together	Hardware is encapsulated by epoxy, which is formed in a mold
Transmitter weight	0.29 ounces	0.30 ounces

Differences		
Item	Candidate Device: Dexcom G6 Continuous Glucose Monitoring System	Predicate Device: Dexcom G6 Continuous Glucose Monitoring System (DEN170088)
Transmitter power supply	Silver oxide 1.55V, 80 mAh battery (not replaceable or rechargeable)	Lithium manganese 3.0V, 140mAh dioxide battery (not replaceable or rechargeable)

I. Special Control/Guidance Document Referenced (if applicable):

Standards referenced

- IEC 62304, Ed 1.1:2015. Medical Device Software – Software Life Cycle Processes.
- IEEE/ANSI C63.27-2017. American National Standard for Evaluation of Wireless Coexistence.
- IEC 60601-1:2012 (Third Edition). Medical Electrical Equipment – Part 1: Requirements for basic safety and essential performance.
- ISO 10993-1:2009. Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5: 2009. Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity.
- ISO 10993-10: 2010. Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-12: 2012. Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

Guidance documents referenced

1. Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s (issued August 12, 2005).
2. eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff (issued December 3, 2015).
3. Refuse to Accept Policy for 510(k)s, Guidance for Industry and Food and Drug Administration Staff (issued January 30, 2018).
4. Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005).
5. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (issued dated October 2, 2014).
6. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," Guidance for Industry and Food and Drug Administration Staff (issued June 16, 2016).

7. Guidance for Industry and FDA Staff, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (issued September 14, 2018).
8. Guidance for Industry and FDA Staff, Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (issued November 30, 2004).
9. General Principles of Software Validation; Final Guidance for Industry and FDA Staff (issued January 11, 2002).

J. Performance Characteristics*:*

The analytical and clinical performance of this device was established in DEN170088. The candidate transmitter has the same overall form, fit, and function as the predicate transmitter, which would not be expected to impact the performance of the device. Transmitter firmware was modified to support the new transmitter hardware with the predicate G6 Algorithm. The sensor, algorithm, receiver, and mobile App (iOS and Android) remain unchanged.

1. Analytical Performance:

   a. Accuracy:

   As established in DEN170088.

   b. Precision/Reproducibility:

   As established in DEN170088.

   c. Linearity:

   As established in DEN170088.

   d. Carryover:

   Not applicable.

   e. Interfering Substances:

   As established in DEN170088.

2. Other Supportive Instrument Performance Data Not Covered Above:

   Clinical performance

   The clinical accuracy performance of the device was established in DEN170088.

   Stability

   Sensor shelf-life stability was established in DEN170088.

The G6 Transmitter has sufficient battery life to function for 3 months as intended following its maximum storage time of 12 months. Battery life testing protocols were reviewed and found to be acceptable.

Biocompatibility

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009, ISO 10993-5: 2009, ISO 10993-10: 2010, and ISO 10993-12: 2012. Cytotoxicity, sensitization, and irritation testing of the G6 Transmitter was performed and the results were found to be acceptable.

Biocompatibility testing of other patient-contacting components of the G6 System was conducted in DEN170088 and found acceptable.

Mechanical Engineering

Transmitter hardware testing provided to support sound mechanical function of the device was reviewed and found acceptable.

Mechanical hardware testing of other components of the G6 System was conducted in DEN170088 and found acceptable.

Electromagnetic Compatibility and Wireless

Electromagnetic Compatibility testing for radio frequency (RF) emissions and electromagnetic immunity was conducted for the G6 Transmitter and demonstrated compliance to IEC 60601-1-2:2014.

Electromagnetic Compatibility testing for the G6 Receiver was established in DEN170088.

Wireless testing for the subject G6 System demonstrated compliance to Federal Communication Commission (FCC), Bluetooth Low Energy (BLE), and Federal Aviation Administration (FAA) requirements. Additionally, testing demonstrated that the subject G6 Transmitter meets all required performance specifications, which include radiofrequency (RF) communication range, wireless coexistence, RF interference, and compatibility with security and logistical systems.

Electrical Safety

The basic safety and essential performance of the subject G6 Transmitter was evaluated and demonstrated compliance to IEC-60601-1:2012 and IEC 60601-1-11:2015.

The basic safety and essential performance of the G6 Receiver was established in DEN170088.

Packaging Integrity/Shipping Integrity

Packaging and shipping validation studies were performed for the subject G6 Transmitter kit and demonstrated that the packaging and distribution packaging configuration(s) withstand the hazards and rigors of the distribution and shipping environment and provide physical protection to the contained product.

Packaging and shipping validation for the G6 Receiver kits and G6 Sensor kits was established in DEN170088.

Cybersecurity

The following information was provided for the device:

- Risk Management
  - A model describing the assets, threats, vulnerabilities, and controls related to the device system was reviewed. Cybersecurity parameters were identified for each asset and included the transmitter, receiver, and smart device applications. The traceability provided was adequate and the risk management was acceptable.
- Planning for Continuing Support
  - A plan for continuing to keep the device secure was provided and found to be complete and adequate.
- Plan for Malware-Free Shipping
  - A plan to ensure the device is shipped without Malware was provided and found to be complete and adequate.

The following supportive instrument performance characteristics were established in DEN170088:

- Detection limit
- Sterility
- Human Factors
- Environmental testing
- Interoperability

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable, and the special controls for this device type under 21 CFR 862.1355.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.