510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k182041

B. Purpose for Submission:

New Device

C. Measurand:

Glucose in Interstitial Fluid

D. Type of Test:

Quantitative, amperometric assay (Glucose Oxidase)

E. Applicant:

Dexcom, Inc.

F. Proprietary and Established Names:

Dexcom G6 Glucose Program Continuous Glucose Monitoring System

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1355
2. Classification: Class II
3. Product code: QDK (integrated continuous glucose monitoring system for non-intensive diabetes management)
4. Panel: Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) 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.

3. Special conditions for use statement(s):

   - This device is for prescription use only.
   - The Dexcom Glucose Program System, which is intended for use in persons with diabetes who do not have a significant risk of hypoglycemia, does not alert or alarm to tell you when your glucose is low (below your target range), high (above your target range), or rapidly changing. Users shold check readings often if they need to know their glucose level.
   - The components of the Dexcom Glucose Program System (sensor, transmitter, or smart device) must be removed prior to magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The Dexcom Glucose Program System has not been tested in those situations.
   - This device is not intended for pregnant women, people on dialysis, or patients receiving intensive medical intervention/therapy.
   - Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the Dexcom Glucose Program System readings and make them look higher than they really are.
   - Sensor placement is important to ensure system performance. Users should choose a site:
     - At least 3 inches from insulin pump infusion set or injection site or previous CGM insertion site
     - Away from waistband, scarring, tattoos, irritation, and bones
     - Unlikely to be bumped, pushed, or laid on while sleeping
   - Store your sensors only between 36° F and 86° F.

4. Special instrument requirements:

   Not Applicable.

I. Device Description:

The Dexcom G6 Glucose Program System in an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose readings which are updated every 5 minutes providing glucose levels and trends. 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). A user must use the Dexcom G6 Glucose Program App (i.e., a mobile medical application) running on a compatible mobile device in order to view glucose data.

G6 GLUCOSE PROGRAM 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.

G6 GLUCOSE PROGRAM TRANSMITTER

The transmitter component 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., mobile device). The transmitter attaches to the sensor and can be re-used for multiple sensing sessions up to three months.

G6 GLUCOSE PROGRAM MOBILE APP
The Dexcom G6 Glucose Program CGM App for Android is the primary display for the system. The Dexcom G6 Glucose Program CGM App is compatible with specific Android devices. A link to a list of compatible devices is included in the instructions for use.

The Dexcom G6 Glucose Program CGM System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from interoperable electronic interfaces. The G6 Glucose Program 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   G6 Continuous Glucose Monitoring System

2. Predicate 510(k) number(s):

   DEN170088

3. Comparison with predicate:

   The Dexcom G6 Glucose Program System is identical to the predicate device with the exception of the user interface (e.g., a new mobile app and no dedicated hardware receiver), and the population that the device is intended for. The predicate device was intended for use by people with diabetes age 2 years and older, whereas the Dexcom G6 Glucose Program System is only intended for those people with diabetes who have a low risk of experiencing severe hypoglycemia.

Similarities		
Item	Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
Device Type	Interoperable CGM	Same
Detection Method	Amperometric electrochemical	Same
Sample Type	Interstitial fluid	Same
Sensor Calibration	Factory calibrated, with optional user calibration	Same
Test Range	40-400 mg/dL	Same
Enzyme	Glucose oxidase	Same
Glucose reading update interval	Autonomously every 5 minutes	Same
Mobile App glucose reading storage	30 days of glucose readings	Same
Wireless communications protocol	Bluetooth Core Specification v4.0	Same
Glucose trend arrows	→, -1 to +1 mg/dL/min ↗, +1 to +2mg/dL/min ↘, -2 to -1 mg/dL/min ↑, +2 to +3 mg/dL/min ↓, -3 to -2 mg/dL/min ↑↑, > +3mg/dL/min ↓↓, < -3mg/dL/min	Same

Similarities		
Item	Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
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 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
Transmitter power supply	Lithium manganese dioxide battery (not replaceable or rechargeable)	Same
Communications range	20 feet	Same

Differences		
Item	Device	Predicate
Intended use population	Persons with diabetes age 2+ years without significant risk of severe hypoglycemia	Persons with diabetes age 2+ years
Alerts and Alarms	Signal loss, sensor failure, transmitter failure	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.
Primary Display Device	Mobile app installed on compatible smart device	Hardware receiver or mobile app installed on compatible smart device
Compatible Smart Devices	Samsung J3	iPhone 5S through iPhone X, and several Samsung phones
Trend Graph Glucose History	6 and 12 hours	1, 3, 6, 12, and 24 hours
Data displayed	Current glucose value, current glucose trend, time in range (user defined ranges)	Current glucose value, current glucose trend, user entered events

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2012; Medical Devices – Application of Risk Management to Medical Devices

ISO 15223-1:2012; Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements

EN 62304:2006/AC:2015; Medical device software – Software life cycle processes

IEC 62366:2014; Medical devices – Application of usability engineering to medical devices

IEC 60601-1:2005 (Ed.3); Medical Electrical Equipment – Part 1: Requiremnts for basic safety and essential performance

L. Test Principle:

The Dexcom G6 Glucose Program CGM 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.

M. Performance Characteristics (if/when applicable):

As established in DEN170088.

The components of the Dexcom G6 Glucose Program System are identical to those of the predicate device except for a new user interface (mobile app) that is specific for the new device.

The analytical and clinical performance of this device is primarily determined by the design of the sensor and transmitter system components, the glucose determination algorithm, and the method of calibration. All of these aspects of the predicate device are unchanged in the candidate device. Therefore the performance characteristics of the candidate device are referenced from the predicate device.

1. Analytical performance:

   a. Precision/Reproducibility:

   As established in DEN170088.

   b. Linearity/assay reportable range:

   As established in DEN170088.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   As established in DEN170088.

   d. Detection limit:

   As established in DEN170088.

   e. Analytical specificity:

   As established in DEN170088.

   f. Assay cut-off:

   Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable.

b. Matrix comparison:

Not applicable. Interstitial fluid is the only indicated matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

As established in DEN170088.

The Dexcom G6 Glucose Program System has a new user interface (mobile app) compared to the predicate device. The new user interface presents similar information to the user (e.g., glucose values and glucose trend information), and users must perform the same critical tasks when using the interface (e.g., entering sensor calibration codes, pairing the transmitter to the app using Bluetooth, and optionally entering blood glucose calibration values). The information provided was adequate to support the substantial equivalence of the new user interface.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Instrument Name:

Dexcom G6 Glucose Program Continuous Glucose Monitoring System

O. System Descriptions:

1. 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 _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   Not Applicable

4. Specimen Sampling and Handling:

   Not Applicable

5. Calibration:

   Though the Dexcom G6 Glucose Program Continuous Glucose Monitoring System does not require user calibration, users have the option to calibrate the device manually (e.g., in situations where users do not have to use the calibration code). Calibration stability was established in DEN170088.

6. Quality Control:

   Not Applicable

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

The following supportive instrument performance characteristics were established in DEN170088:

- Biocompatibility
- Sterility

- Human Factors
- Mechanical Engineering
- Electromagnetic Compatibility and Wireless
- Electrical Safety
- Environmental Testing
- Shelf Life Stability
- Packaging Integrity / Shipping Integrity
- Interoperability
- Contact Resistance

Cyber Security:

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 provided reviewed. Cyber security parameters were identified for each asset and included the transmitter, receiver, and smart device applications. Traceability was provided and was adequate. 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.

Q. 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.

R. Conclusion:

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