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

A. 510(k) Number:

K182405

B. Purpose for Submission:

New Device

C. Measurand:

Glucose in interstitial fluid

D. Type of Test:

Quantitiative, amperometric assay (Glucose Oxidase)

E. Applicant:

Dexcom, Inc.

F. Proprietary and Established Names:

Dexcom Pro Q Continuous Glucose Monitoring System

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1355

2. Classification: Class II

3. Product code: QDL

4. Panel: Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use.

2. Indication(s) 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 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.

3. Special conditions for use statement(s):
   - This device is for prescription use only. Results should be interpreted only by qualified health care professionals.
   - The components of the Dexcom Pro Q System (sensor and transmitter) must be removed prior to magnetic resonance imaging (MRI), computed tomography (CT) scan, or high frequency electrical (diathermy) treatment. The Dexcom Pro Q System has not been tested in those situations.
   - 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.
   - 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 irritated skin, tattoos, near waistband, bones, or scarring.
     - Unlikely to be bumped, pushed or laid on while sleeping.
   - Store sensors only between 36° F and 86° F. Do not store sensors in the freezer.

4. Special instrument requirements:
Not applicable.

I. Device Description:

The Dexcom Pro Q Continuous Glucose Monitoring (CGM) System is a glucose recording device that measures and logs glucose readings at five-minute intervals for up to ten days. The Pro Q System consists of a sensor and a Bluetooth Low Energy (BLE) transmitter. The sensor is a small, flexible wire inserted into the subcutaneous tissue where it converts glucose into electrical current. The transmitter, which is connected to the sensor and worn on the body, samples the electrical current produced by the senor and converts these measurements

into glucose readings using an onboard algorithm. The system does not have a way to display glucose values in real-time and cannot be authorized to do so. A user must use an authorized extraction device after the sensor session has ended to extract and view data collected by the Pro Q Transmitter.

Pro Q 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 is identical to the predicate G6 sensor.

Pro Q CGM TRANSMITTER

The Pro Q CGM Transmitter is a miniature radio transmitter that incorporates data processing functionality. The transmitter contains a Bluetooth radio transceiver to enable transmittance of stored data once the sensor session has ended. The transmitter attaches to the sensor and is not reusable. The transmitter hardware is unchanged from the predicate G6 transmitter, with the exception of a firmware (see above). An authorized extraction device must be used to extract and view data collected by the Pro Q Transmitter.

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 Pro Q System is largely identical to the predicate device with the exception of aspects related to data storage and display; the device stores glucose data for the entire sensor wear period and data are intended for retrospective analysis by a healthcare provider using an authorized extraction device; by contrast, the predicate device includes a display that provides users with glucose information in real-time. The Dexcom Pro Q System includes only a sensor and transmitter, and patients must see their healthcare provider for insertion and removal of the sensor.

Similarities		
Item	Dexcom Pro Q Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
Intended Use	Intended to automatically measure glucose in bodily	Same

Similarities		
Item	Dexcom Pro Q Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
	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 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.	
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Detection Method	Amperometric electrochemical	Same
Sample Type	Interstitial fluid	Same
Test Range	40-400 mg/dL	Same
Enzyme	Glucose oxidase	Same
Glucose reading update interval	Autonomously every 5 minutes	Same
Wireless communications protocol	Bluetooth Core Specification v4.0	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 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	Dexcom Pro Q Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
Application	Retrospective discovery, analysis and interpretation of glucose values	Real-time glucose monitoring
System Components	Sensor/Applicator and Transmitter	Sensor/Applicator, Transmitter, Display Device (Mobile App and Receiver)
Data Presentation	**Real-Time Data:** no real time data are presented to users. **Historical Glucose Data:** The glucose data collected throughout the entire wear-period is presented to the user and healthcare professional after the sensor session has ended.	**Real-Time Data:** users are presented with real-time glucose values and glucose rate of change. **Historical Glucose Data:** Users can view their previous three, six, twelve, or twenty-four hours of glucose data.
Glucose Value Transmission Interval	Every 5 minutes (glucose values are collected every 30 seconds and stored for later data extraction and analysis)	Every 5 minutes (glucose values are collected and sent to the display device)
Features	Analysis with a healthcare professional: Extraction via authorized tool	Real time data and connect to Dexcom Share app:
User Interaction	The system includes an automatic applicator for sensor insertion. The system does not include a display device or require any user input to start a session or calibrate the system.	The system includes an automatic applicator for sensor insertion. During system start-up and prior to the start of each sensor session, the system requires the user to input the sensor code into the display device for calibration. User may also choose to calibrate using blood glucose values. The user can enter an optional calibration at any time, even after the sensor

Differences		
Item	Dexcom Pro Q Continuous Glucose Monitoring System (Candidate)	Dexcom G6 Continuous Glucose Monitoring System (Predicate)
		code has been entered.
Compatibility with intended environments	Compatible authorized extraction device	Compatible with iPhone 5S through iPhone X, Samsung Note 5, Note 8, Galaxy S6-S9, J3, Google Pixel, LG G5-G6 Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above Compatible with authorized interoperable devices, including automated insulin delivery devices.
Calibration	Factory calibrated (no user calibration code necessary), no user calibration possible	Factory calibrated (user enters calibration code) and optional user calibration

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

ISO 13485:2003; Medical Devices-Quality management systems-Requirements for regulatory purposes

ISO 14971:2012; Medical devices – Applications of risk management to medical devices

IEC 62304, Ed. 1.1:2015; Medical Device Software – Software Lifecycle Processes (2006+AMD1:2015)

IEC 62366 Ed. 1.1:2014; Medical Devices – Application of usability engineering to medical devices, Edition 1.1 (2014)

IEC 60601-1:2005; Medical Electrical Equipment – Part 1: Requirements for basic safety and essential performance

ISO 15223-1:2012; Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s, dated August 2005

Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005

General Principles of Software Validation; Final Guidance for Industry and FDA Staff, dated January 11, 2002

Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices, dated September 9, 1999

Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf Software, dated January 14, 2005

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, dated October 2, 2014

Applying Human Factors and Usability Engineering to Medical Devices –Guidance for Industry and FDA Staff, dated February 3, 2016

Guidance for Industry and FDA Staff Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, dated November 30, 2004

L. Test Principle:

The Dexcom Pro Q 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 recorded and stored on the transmitter until the data is extracted by a qualified healthcare professional for interpretation and use.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      The Pro Q CGM uses the same sensor, transmitter, and algorithm as the predicate device, the Dexcom G6 Continuous Glucose Monitoring System. Therefore, performance was evaluated under DEN170088. Please see the decision summary for the Dexcom G6 Continuous Glucose Monitoring System (DEN170088)

   b. *Linearity/assay reportable range:*
      The reportable range for the Pro Q CGM is 40 to 400 mg/dL. Data supporting this claimed measurement range was reviewed under DEN170088. Please see the decision summary for DEN170088.

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

The Pro Q CGM sensor has a storage shelf-life of 12 months and testing is on-going. Shelf life was evaluated at 32^0-86^0 F and 10-90% relative humidity.

The Pro Q Transmitter has sufficient battery life to function for 3 months as intended following its maximum storage time of 8 months. Shelf life was evaluated at 32^0-113^0 F and 10-95% relative humidity.

d. *Detection limit:*
If a glucose measurement is less than 40 mg/dL, the result is displayed by the system as 'Lo'. If a glucose measurement exceeds 400 mg/dL, result is displayed as 'Hi'. Data supporting this claimed measurement range was generated in the clinical study described in Section L(3) below. Data supporting this was reviewed under DEN170088. Please see the decision summary for DEN170088.

e. *Analytical specificity:*

Data supporting the analytical specificity was reviewed under DEN170088. Please see the decision summary for 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:

Data supporting clinical studies was reviewed under DEN170088. Please see the decision summary for DEN170088.

4. Expected values:

Not applicable.

N. Instrument Name:

Dexcom Pro Q 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 _____

1. Specimen Identification:

   Not applicable

2. Specimen Sampling and Handling:

   Not applicable

5. Calibration:

   Not applicable (factory calibrated).

6. Quality Control:

   Not applicable.

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

Biocompatibility:
Data supporting biocompatibility was reviewed under DEN170088. Please see the decision summary for DEN170088.

Sterility:
Data supporting sterility was reviewed under DEN170088. Please see the decision summary for DEN170088.

Mechanical Engineering:
The physical dimensions and hardware are identical to the predicate device. Data supporting the mechanical engineering was reviewed under DEN170088. Please see the decision summary for DEN170088.

Electromagnetic Compatibility:
Data supporting electrocompatibility testing was reviewed under DEN170088. Please see the decision summary for DEN170088.

Electrical Safety:
Data supporting electrical safety was reviewed under DEN170088. Please see the decision summary for DEN170088.

Environmental Testing:
Data supporting environmental testing was reviewed under DEN170088. Please see the decision summary for DEN170088.

Shelf-Life Stability:
Data supporting the shelf life stability was reviewed under DEN170088. Please see the decision summary for DEN170088.

Packaging Integrity/Shipping Integrity:
Packaging and shipping specifications are the same as the predicate. Data supporting the package and shipping integrity was reviewed under DEN170088. Please see the decision summary for DEN170088.

Interoperability:
A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events). The device cannot be authorized for real-time data display. In addition, after data extraction, glucose data collected by the Dexcom Pro Q System must pass through Dexcom's cloud-based data infrastructure before being made available for display or analysis. Access to the data is controlled by Dexcom, through user credentials.

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 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.

Contact Resistance:

Data supporting the contact resistance was reviewed under DEN170088. Please see the decision summary for DEN170088.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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