EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR STUDIO on the Cloud Data Management Software

DECISION SUMMARY

A. DEN Number:

DEN140016

B. Purpose for Submission:

De novo request for adjunct data management software

C. Measurand:

Not applicable. The submission is for a continuous glucose monitor data management software device.

D. Type of Test:

Diabetes data management system

E. Applicant:

Dexcom, Inc.

F. Proprietary and Established Names:

STUDIO on the Cloud Data Management Software

G. Regulatory Information:

1. Regulation: 21 CFR 862.2120, Continuous glucose monitor data management system.
2. Classification: Class I, exempt
3. Product code: PHV
4. Panel: Chemistry (75)

H. Intended Use:

1. Intended use(s):

The STUDIO on the Cloud Data Manager Software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical CGM data to support effective diabetes management. It is intended for use as an accessory to CGM devices with data interface capabilities.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription home use.

   This device is intended for display of retrospective glucose data and not for real-time display of glucose results.

   This device is not intended for making treatment decisions.

   This device is not intended for calculating insulin or other drug doses.

   This device is not intended for controlling insulin pumps or other drug delivery systems.

4. Special instrument requirements:

   Dexcom G4 PLATINUM Continuous Glucose Monitoring System

I. Device Description:

The STUDIO on the Cloud Data Management ("STUDIO") Software is comprised of a data analysis and storage platform, report generation software, and an information delivery service.

Specifically, the proposed STUDIO Software performs the following functions:

- Data Upload: the SweetSpot Fetch Utility application will be used to access data from a Receiver, using either Mac or PC operating systems;
- Data Analysis: certain SweetSpot Platform functions will be used to validate, aggregate, and analyze (e.g., correlate) CGM data, and to create charts and reports that mimic the current STUDIO Pattern and Glucose Strips charts and reports;
- Reports: The current STUDIO Pattern charts will be displayed on the user's computer screen, and both the Pattern and Glucose Strip charts can be saved to the user's computer in PDF format. Both reports may be printed by the user as a PDF document.

The STUDIO Software uses only retrospective data stored on the G4 PLATINUM device to create statistical reports, and does not make treatment recommendations.

J. Standard/Guidance Documents Referenced:

1. Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999
2. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
3. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry & FDA Staff, June 13, 2013
4. Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 14, 2005
5. General Principles of Software Validation, Final Guidance for Industry and FDA Staff, January 11, 2002
6. Guidance for Industry and Food and Drug Administration Staff, Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, March 28, 2012
7. ISO 14971:2012 Medical devices – Application of risk management to medical devices
8. IEC/TR 80002-1:2009 Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software
9. ANSI/AAMI/IEC 62304:2006 Medical device software – Software life cycle processes
10. ISO 13485: Quality Systems - Medical Devices - System Requirements for Regulatory Purposes
11. U.S. Food and Drug Administration, 21 CFR Part 820: Quality System Regulation
12. NIST SP 800-53 rev3: Recommended Security Controls for Federal Information Systems and Organizations
13. HIPAA: Health Insurance Portability and Accountability Act

K. Test Principle:

Not applicable.

L. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Reproducibility/Precision

   Not applicable.

   b. Linearity/assay reportable range:

Not applicable.

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

Not applicable.

d. Detection limit

Not applicable.

e. Analytical specificity:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

A usability study was performed with Forty Four (44) lay and professional users with varying demographic characteristics (age, sex, and education level). The intent of the study was to verify software ease of use and label comprehension. The study determined that 96% of assigned tasks were able to be completed by users without assistance.

4. Expected Values

Not applicable.

M. Instrument Names:

STUDIO on the Cloud Data Management Software

N. System Description:

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 ____or No __X____.

2. Software:

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

   Yes ___X_____ or No _____

2. Specimen Identification:

   Not Applicable

3. Specimen Sampling and Handling:

   Not Applicable

4. Calibration:

   Not Applicable

5. Quality Control:

   Not Applicable

O. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

1. The following documentation related to the STUDIO on the Cloud Data Management Software was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, architecture design chart, software design specification, traceability analysis, software development environment description, verification and validation testing, and revision level history.

2. Bench Testing was perfomed using data from forty (40) G4 PLATINUM receivers. CGM data were uploaded from the receivers using the STUDIO on the Cloud Data Management Software and were compared to the same data downloaded to a PC. All data fields were reported to be 100% accurate.

P. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 801, 21 CFR Part 809, and 801.109.

Q. Identified Potential Risks and Required Mitigations

Table – Identified Risks and Required Mitigations

Identified Risk	Required Mitigation
Device malfunction (e.g., incorrect data analysis, etc.)	General controls, including design controls

Device malfunction (e.g., incorrect data analysis, etc.) may lead to diabetes mismanagement and poor glycemic control. This risk can be adequately mitigated by general controls, including design controls and restriction as a prescription device that must comply with 21 CFR 801.109.

R. Benefit/Risk Analysis

Summary	
Summary of the Benefit(s)	The STUDIO on the Cloud Data Management Software is convenient to use since it analyzes and correlates several sources of diabetes management-relevant information (e.g. user glucose levels, meals, insulin delivery, and exercise data) into one software program. The data sorting and presentation functions of the STUDIO on the Cloud Data Management Software provide patients and their doctors access to a more complete clinical picture of a patient's current disease, as well as of the impact of past diabetes management decisions on a patient's glucose levels. The convenience of using the device should translate into better record-keeping compliance by the patient, and the greater access provided to data should assist the patient and their physician with the identification of the patient's unique glucose excursion triggers; together, these benefits should allow patients and their doctors to make rational modifications to the patient's diabetes management plan, with the goal of achieving better glycemic control.

Summary of the Risk(s)	Device malfunction may lead to diabetes mismanagement and poor glycemic control. Decisions made based on incorrect data or faulty analyses may put the patient at risk of more frequent acute episodes of hypoglycemic and/or hyperglycemic excursions. These episodes increase the likelihood of hospitalization and/or death. Chronic poor glycemic control could lead to irreversible diabetes-related sequelae (e.g. retinopathy, neuropathy, nephropathy and arteriosclerosis). These risks can be adequately mitigated by the sponsor's verification and validation and design control activities which ensure that the risk of malfunction is very low. Continuous glucose meters are only approved for tracking and trending; therefore another risk is that users could modify their current insulin dosage based directly on current CGM glucose values provided by the STUDIO on the Cloud Data Management Software. This risk is mitigated by product labeling which states that users should not make changes in their treatment program without talking to their healthcare providers. In addition, only retrospective CGM glucose values are provided by the software, so real-time CGM glucose values are not readily available to users. Risks are mitigated by general controls, including requiring design controls and restriction as a prescription device that must comply with 21 CFR 801.109.
Summary of Other Factors	Patients are willing to tolerate the low risk associated with use of the STUDIO on the Cloud Data Management Software because they benefit from a substantial improvement in the analysis and correlation of retrospective continuous glucose monitoring information (e.g. glucose values over time, paired with meal, exercise, and insulin bolus information), which can be used by the patients and their doctors to assist in making adjustments to their diabetes management program, with the goal of reducing glucose excursions and maintaining proper glycemic control.
Conclusions Do the probable benefits outweigh the probable risks?	Yes. The device is likely to provide benefits in improved diabetes management with a low associated risk.

S. Conclusion:

The information provided in this *de novo* submission is sufficient to classify this device into class I, exempt from premarket notification requirements subject to the limitations in 21 CFR 862.9, under regulation 21 CFR 862.2120. As a software containing device, this device type is also subject to design controls. FDA believes that applicable general controls, including design controls, provide reasonable assurance of the safety and effectiveness of the device type. The device is classified under the following:

Product Code:	PHV
Device Type:	Continuous glucose monitor data management system
Class:	I (general controls)
Regulation:	21 CFR 862.2120

(a) *Identification*. A continuous glucose monitor data management system is an electronic device intended to acquire, process, and correlate retrospective data from a continuous glucose monitoring device. This device is intended to be used by patients or their healthcare providers when determining therapeutic strategies. A continuous glucose monitor data management system is not a drug dose calculator and does not provide treatment recommendations.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.