

**EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
Dexcom Share Direct Secondary Displays**

DECISION SUMMARY

This decision summary corrects the decision summary dated January 23, 2015.

A. DEN Number:

DEN140038

B. Purpose for Submission:

De Novo request for evaluation of automatic class III designation for the Dexcom Share Direct Secondary Displays

C. Measurand:

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

D. Type of Test:

Continuous glucose monitor secondary display device

E. Applicant:

Dexcom, Inc.

F. Proprietary and Established Names:

Dexcom Share Direct Secondary Displays

G. Regulatory Information:

1. Regulation:
21 CFR 862.1350, Continuous glucose monitor secondary display device
2. Classification:
Class II
3. Product code:
PJT
4. Panel:

H. Intended Use:

1. Intended use(s):

Same as Intended use above

2. Indication(s) for use:

The purpose of Dexcom Share Direct Secondary Displays is to notify another person, the Follower, of the patient's Dexcom G4 PLATINUM Continuous Glucose Monitoring System sensor glucose information. The Secondary Displays is intended for providing secondary notification of a continuous glucose monitoring system and does not replace real time continuous glucose monitoring (G4 PLATINUM System) or standard home blood glucose monitoring.

The Dexcom Share Direct Secondary Displays is not intended to modify or analyze data received from the continuous glucose monitor system. Nor is it intended to instruct, or to transmit information to the continuous glucose monitor system. The Dexcom Share Direct Secondary Displays is not intended to serve as a replacement for a primary display device for a continuous glucose monitoring system. The Dexcom Share Direct Secondary Displays is not intended to receive information directly from the sensor or transmitter of a continuous glucose monitoring system.

3. Special conditions for use statement(s):

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.

Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.

This device is not intended to replace self-monitoring practices advised by a physician.

4. Special instrument requirements:

Dexcom G4 PLATINUM Continuous Glucose Monitoring System

I. Device Description:

The Dexcom Share Direct Secondary Displays is a family of mobile applications (apps) that allows for the real-time monitoring of data from the Bluetooth enabled "Dexcom G4 PLATINUM Receiver with Share" by a third party by means of display on a compatible third party device with an internet connection. The system consists of two apps: one installed on

the Continuous Glucose Monitor (CGM) patient's phone (the "Share2" app) and one installed on the phone of another person (the "Follow" app). Using the Share2 app, the patient can designate people ("Followers") with which to share their CGM data. The Share2 app receives real-time CGM data directly from the CGM receiver and transmits it to the Dexcom Cloud server (a web-based storage location). The Follow app, installed on a Follower's phone, can then download the CGM data and display it in real time.

The Dexcom Share Direct Secondary Displays was preceded by the Dexcom Share System. In the Dexcom Share Direct Secondary Displays, the CGM receiver is Bluetooth enabled and can communicate directly with the Share2 app on a patient's smart phone. In the predecessor, the Dexcom Share System, the CGM receiver must be placed in a Bluetooth enabled docking station which in turn transmits real-time CGM data to the Dexcom Share app on the CGM patient's mobile device. The Share app then transmits the data via the internet to the Dexcom Share Cloud, from which the Follow app installed on a follower's phone can retrieve the data. The Dexcom Share Direct Secondary Displays eliminates the need for a docking station: the CGM receiver transmits information directly to the Share2 app on the CGM patient's phone. The Share2 app functions identically to the Share app, with the exception that it cannot communicate with the docking station. The same Follow app is used in both cases, as its function has not changed.

The Dexcom Share Direct Secondary Displays device performs the following functions:

- Share2 App:
 - Transmit real-time glucose values and ancillary information (e.g. trends, alarms and notifications) to a third-party device/display/data storage system.
- Follow App:
 - Receive and display real-time glucose values.
 - Receive and display glucose trend information.
 - Receive and deliver notifications and alarms.

The Dexcom Share Direct Secondary Displays is used for secondary real-time monitoring of a patient's continuous glucose monitoring system. It is not intended to be the primary method of patient monitoring and it does not make treatment recommendations. It does not receive information directly from the sensor or primary transmitter of the CGM system; it receives information from the primary display device (in this case, the CGM receiver). It does not serve as a replacement for a primary display device. It does not make treatment recommendations, calculate insulin doses, or control any other medical devices.

J. Standard/Guidance Documents Referenced:

1. ISO 14971 Medical devices - Application of Risk Management to Medical Devices.
2. IEC 60601-1 Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance
3. Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. October 2, 2014
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Gui>

[danceDocuments/UCM356190.pdf](#)).

4. Guidance: Guidance on Medical Device Patient Labeling. April 19, 2001 (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf>).

K. Test Principle:

Not applicable.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

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 clinical study was conducted for the Dexcom Share System (P120005/S009), which

was the predecessor to the Dexcom Share Direct Secondary Displays. The interface and functionality of the Share and Follower apps remains unchanged between these two systems, so it was determined that a new clinical study was not required for the Dexcom Share Direct Secondary Displays.

The study population used in the evaluation of the Dexcom Share System consisted of 20 participant pairs (Sharer + Follower) who pre-qualified as representative users of one or both of the Dexcom Share and Follow Apps. User groups were divided as follows:

1. Hypo-unaware type 1 diabetes (T1D) adults with CGM experience and their adult follower
2. Self-managing T1D children with CGM experience and their parent follower
3. Parents of non-self-managing T1D children with CGM experience

The participants were asked to complete a series of task-based scenarios and their responses were scored. The scenarios involved simulated use of the Dexcom Share System, including set up of the system hardware components as well as installation and use of the Dexcom Share & Follow Apps. There was no use of lancing devices, blood, simulated wearing of sensor pods on skin or actual dosing of insulin.

Based on the usability testing, the Dexcom Share System has been found to be adequately safe and effective for the intended users, its intended use, and use environment.

4. Expected Values

Not applicable.

M. Instrument Names:

Dexcom Share Direct Secondary Displays

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 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 _____

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 Follow App 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 performed to show that data is transmitted accurately. Data from thirty (30) G4 PLATINUM Receivers with Share were uploaded from the Receivers to compatible Apple devices using the Share2 app and Follow app. Data on the Follow app were shown to be identical to the data on the receiver.

P. Proposed Labeling:

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

Q. Identified Risks to Health and Required Mitigations

Identified Risks to Health	Required Mitigations
Incorrect glucose value reported on the secondary display or glucose value missed due to cybersecurity breach.	Special control (1)
Treatment recommendations are made based on data presented by secondary display device.	Special control (2)
Individual with diabetes becomes overly reliant on “followers” for monitoring their glucose levels.	Special control (3)

R. Benefit/Risk Analysis

Summary	
Summary of the Benefit(s)	Secondary display devices are convenient to use because they allow for the automated sharing of glucose data for remote patient monitoring. The data sharing allows “followers” to stay informed and assured of the well-being of the patient without needing to be in constant contact. Additionally, data sharing may provide patients themselves with a more convenient way to access data from their continuous glucose monitoring sensor. The convenience of the device should translate into better monitoring of the patient’s status and more peace of mind for those interested in the patient’s well-being. It is also possible for a caregiver to notice if a person is experiencing hypo/hyperglycemia and facilitate intervention if the person cannot do so.

<p>Summary of the Risk(s)</p>	<p>Device malfunction may lead to diabetes mismanagement and poor glycemic control. Decisions made based on incorrect data may put the patient at risk of 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). It is also possible that patients who are unable to manage their diabetes will not receive timely interventions without the availability of remote monitoring via a real-time secondary display. These risks can be adequately mitigated by the special control that requires that devices being marketed must include measures to protect against unauthorized access to data and unauthorized modification of data, along with the sponsor’s verification and validation and design control activities which ensure that the risk of malfunction is very low.</p> <p>Another risk is patients might become overly reliant on “followers” for monitoring their glucose levels and cease or reduce self-monitoring. This risk is mitigated by the special control that labeling for the device a limitation that states “This device is not intended to replace self-monitoring practices advised by a physician.”</p> <p>Continuous glucose meters are only approved for tracking and trending; therefore another risk is that patients could modify their current insulin dosage based directly on current continuous glucose monitor values provided by the secondary display device. This risk is mitigated by the special controls requiring product labeling to state that patients should only make treatment decisions that are consistent with the labeling of the parent continuous glucose monitor and the recommendations of their physician. Risks are further mitigated by general controls, including requiring design controls.</p>
<p>Summary of Other Factors</p>	<p>Patients are willing to tolerate the low to moderate risk associated with use of secondary display devices because they benefit from the ability to keep interested parties up to date on their disease state in real time, with the goal of providing improved patient monitoring and maintaining proper glycemic control.</p>
<p>Conclusions Do the probable benefits outweigh the probable risks?</p>	
<p>Yes. The device is likely to provide benefits in improved diabetes monitoring with a low associated risk.</p>	

S. Conclusion:

The information provided in this *de novo* submission is sufficient to classify this device into class II under regulation 21 CFR 862.1350. FDA believes that the stated special controls and 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: PJT

Device Type: Continuous glucose monitor secondary display
Class: II (special controls)
Regulation: 21 CFR 862.1350

(a) *Identification.* A continuous glucose monitor secondary display is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data. It must not be capable of serving as a stand-alone primary display device. The primary display device, which is not a part of the continuous glucose monitor secondary display, directly receives the glucose data (for example, it communicates directly with transmitter) from the continuous glucose meter, which is not a part of the continuous glucose monitor secondary display, and is the primary means of viewing the continuous glucose monitor data and alerting the patient to a low or high glucose value. A continuous glucose monitor secondary display can be used by caregivers of people with diabetes to monitor a person's continuous glucose monitoring data. A device is not a continuous glucose monitor secondary device if the data from the primary display device is modified (for example predicting future glucose values) or the patient can use the secondary display in lieu of a primary display device (for example the primary display device is blinded or the primary display does not have to be near the person wearing the sensor and transmitter).

(b) *Classification.* Class II (special controls). A continuous glucose monitor secondary display must comply with the following special controls:

1. Devices being marketed must include appropriate measures to protect against unauthorized access to data and unauthorized modification of data.
2. The labeling must prominently and conspicuously display a warning that states "Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system."
3. The labeling for the device must include a limitation that states "This device is not intended to replace self-monitoring practices advised by a physician."