

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

A. 510(k) Number:

K151236

B. Purpose for Submission:

New device

C. Manufacturer and Instrument Name:

Medtronic Minimed, Inc.

MiniMed Connect System

D. Type of Test or Tests performed:

Continuous glucose monitor and insulin pump secondary display device

E. System Descriptions:

1. Device Description:

MiniMed Connect is a secondary display of continuous glucose monitor and/or insulin pump data on a suitable consumer electronic device for insulin pump patients and their care partners. This system is designed as an optional accessory to compatible sensor-augmented pump systems. MiniMed Connect consists of a MiniMed Connect app (for a local secondary display), the CareLink Connect module of CareLink Personal (for a remote secondary display), and the MiniMed Connect uploader (for data transmission to the local app).

The MiniMed Connect uploader is a small, battery-powered, ambulatory device that is carried with the patient in near proximity to the insulin pump. Its rechargeable battery is charged as needed (approximately once a day) using a USB Charger that accompanies the device. The MiniMed Connect uploader receives continuous glucose monitor and/or insulin pump data from the sensor-augmented insulin pump using a proprietary 916.5 MHz RF, and then converts it into a 2.4 GHz Bluetooth Low Energy (BLE) format. This BLE formatted data can then be read by the MiniMed Connect app installed on a compatible consumer electronics device with BLE capabilities.

The MiniMed Connect app reads the BLE data transmission and displays it on the patient's compatible consumer electronic device. The MiniMed Connect app then uploads the continuous glucose monitor and/or insulin pump data to CareLink Connect, the remote monitoring module of CareLink Personal. Authorized care partners can access CareLink Connect to view the patient's continuous glucose monitor and/or insulin pump data through an Internet-enabled consumer electronic device for the purpose of passive monitoring.

Accessories associated with this system include:

- USB Charger (for charging the MiniMed Connect uploader)

2. Principles of Operation:

The MiniMed Connect System is a real time secondary display for Continuous Glucose Monitor data and Insulin Pump data. The MiniMed Connect System is an accessory to compatible Continuous Glucose Monitors and Insulin Pumps.

The MiniMed Connect System local mobile application is currently supported on the Apple iOS Operating System version 8.

The MiniMed Connect System web-based remote application, CareLink Connect, can be accessed from any internet browser with an internet-connected consumer electronic device (e.g. iPhone, iPod Touch, Android Phone, personal computer (PC), Macintosh, etc.).

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:

Specimen Identification is based on time and date of testing.

5. Specimen Sampling and Handling:

Not applicable. There is no specimen handling in this device; the device transfers data only.

6. Calibration:

Not applicable

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 §862.1350

2. Classification:

Class II, exempt from the premarket notification requirement subject to the limitations in 21 CFR 862.9

3 Product code:

PJT: Continuous glucose monitor secondary display

PKU: Insulin pump secondary display

4. Panel:

Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

MiniMed Connect is intended to provide a secondary display of continuous glucose monitoring and/or insulin pump data on a suitable consumer electronic device to care partners and users of a MiniMed 530G system or Paradigm REAL-Time Revel system for the purposes of passive monitoring.

MiniMed Connect system is not intended to replace the real-time display of continuous glucose monitor and/or insulin pump data on the primary display device (i.e., the sensor-augmented pump). All therapy decisions should be based on blood glucose measurements obtained from a blood glucose meter.

The MiniMed Connect is not intended to analyze or modify the continuous glucose monitor data and/or insulin pump data that it receives. Nor is it intended to control any function of the connecting continuous glucose monitor system and/or insulin pump. The MiniMed Connect is not intended to serve as a replacement for a primary display device for the continuous glucose monitoring system and/or insulin pump data. The MiniMed Connect is not intended to receive information directly from the sensor or transmitter of a continuous glucose monitoring system.

2. Special conditions for use statement(s):

For Over-the-counter use

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.

H. Substantial Equivalence Information:1. Predicate device name(s) and 510(k) numbers:

Dexcom Share Direct Secondary Displays, DEN140038

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	Medtronic MiniMed Connect (K151236)	Dexcom Share Direct Secondary Displays (DEN140038)
Intended Use	MiniMed Connect is intended to provide a secondary display of CGM and insulin pump information on a suitable consumer electronic device to care partners and users of a MiniMed 530G system or Paradigm REAL-Time REVEL for the purposes of passive monitoring. It is not intended to replace the real-time display of continuous glucose monitor and/or insulin pump data on the primary display device.	The purpose of the continuous glucose monitor secondary display is to notify another person, the follower, of the patient's continuous glucose monitor system sensor glucose information in real time. The secondary display is intended for providing secondary notification of a continuous glucose monitoring system and does not replace primary real time continuous glucose monitoring or standard home blood glucose monitoring.
Sterilization	None	Same
Primary or Secondary Display	Secondary	Same
Data Transmission to Local App	BLE	Same
Data Transmission from Local App to Remote App	Wi-Fi or Cellular Data	Same
Local App / Operating System	Native application for iOS device	Same
Remote App / Operating System	Web-based application that can be viewed on any mobile operating system	Native application support for iOS; additional operating systems under development

Similarities		
Item	Device	Predicate
Web Server	Data storage	Same
Data Upload	Local app receives data every 5 minutes; sends data to the web server and remote app every 5 minutes	Same
	Medtronic MiniMed Connect (K151236)	Dexcom Share Direct Secondary Displays (DEN140038)
Alerts / Notifications – local app	No alarms/alerts for local app, alarms/alerts for remote app only	Same
Alerts / Notifications – remote app	User configurable alarms/alerts	Same

Differences		
Item	Device	Predicate
	Medtronic Minimed Connect (K151236)	Dexcom Share Direct Secondary Displays (DEN140038)
BLE Converter	Hardware component (i.e., MiniMed uploader) converts 916.5 MHz proprietary RF from primary display (i.e., pump) to 2.4 GHz BLUE	BLUE installed within primary display (i.e., receiver); no additional hardware
Display Contents	CGM and/or insulin pump data	CGM

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

- EN 60601-1 – Medical electrical equipment – Part1: general requirements for basic safety and essential performance
- IEC 60601-1-2 – Medical electrical equipment – Part 2: general requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – requirements and tests (edition 3)
- IEC 60601-1-6 - Medical electrical equipment – Parts 1-6: general requirements for basic safety and essential performance – collateral standard: usability
- IEC 60601-1-11 Medical electrical equipment – Parts 1-11: general requirements for basic safety and essential performance – collateral standard: Medical electrical systems used in the home healthcare environment
- IEC 62304 – Medical device software – software life cycle process
- IEC 62366 – Medical devices – application of usability engineering to medical devices
- ISO 14971 – Medical devices – application of risk management
- ISO 15223-1 – Medical devices – symbols to be used with medical devices labels, labeling, and information to be supplied – part 1: general requirements

J. Performance Characteristics:1. Analytical Performance:

- a) *Accuracy:*
Not applicable.
- b) *Precision/Reproducibility:*
Not applicable.
- c) *Linearity:*
Not applicable.
- d) *Carryover:*
Not applicable.
- e) *Interfering Substances:*
Not applicable.

2. Other Supportive Instrument Performance Data Not Covered Above:

1. The sponsor performed a bench study in order to demonstrate that the device transmitted and stored accurately and securely. Testing was also carried out to verify that corrupted data could not be displayed. All data was shown to be accurately transmitted by the device. It was verified that the data is stored on the mobile device in an encrypted state, and that it is transmitted over secure channels. When purposely corrupted data was transmitted to the application, the application correctly did not display that information.
2. The MiniMed Connect system was evaluated for usability using a representative population. Study participants consisted of twenty-five (25)

patients with diabetes mellitus, currently undergoing treatment with a MiniMed Paradigm pump (i.e., Revel or 530G) and with continuous glucose monitoring capability.

Study participants were presented with typical tasks associated with use of the device. Selected tasks that were identified to be either high or medium usability risk during task analysis were assessed. Use errors and near errors committed by participants during the course of the study were collected. The type, frequency, and anticipated consequences of these errors were assessed and assigned a usability risk severity according to the task analysis. Subjective feedback was also collected on the observed errors and included in the analysis.

The use errors reported during the study were judged to be nuisance issues, and involved users having difficulty pairing the device with the mobile app. These errors were primarily caused by users not reading the provided user guide before attempting a task.

Based on the results of this testing, the MiniMed Connect system was determined to be adequately safe and effective for its intended use and the intended environment.

3. The results of a Flesch-Kincaid readability analysis for the MiniMed Connect system user guide were provided. The user guide achieves a score of Flesch-Kincaid grade level equivalent to 8th grade, which is in the acceptable range.
4. The sponsor provided the appropriate documentation certifying that mechanical, electrical, and electromagnetic testing had been evaluated and found to be compliant.

K. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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