DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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MEDTRONIC MINIMED, INC.
LIANE R. MILLER
SENIOR REGULATORY AFFAIRS SPECIALIST
18000 DEVONSHIRE STREET
NORTHRIDGE, CA 91325

May 19, 2015

Re: K151236
Trade/Device Name: MiniMed Connect
Regulation Number: 21 CFR 862.1350
Regulation Name: Continuous Glucose Monitor Secondary Display
Regulatory Class: II
Product Code: PJT, PKU
Dated: May 8, 2015
Received: May 11, 2015

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Dianostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151236

Device Name
MiniMed Connect

Indications for Use *(Describe)*
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 purpose of passive monitoring.

MiniMed Connect system is not intended to replace the real-time display of continuous glucose monitoring 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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the MiniMed Connect system is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendations outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, dated 28 July, 2014.

I. SUBMITTER [807.92(a)(1)]

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Date Prepared: May 19, 2015

II. DEVICE [807.92(a)(2)]

Name of Device:	Medtronic MiniMed® Connect (MMT-7000, MMT-7001, MMT-7333)
Common or Usual Name:	MiniMed® Connect
Classification Name:	Continuous Glucose Monitor Secondary Display
Product Code:	PJT, PKU
Regulatory Class:	2
Submission Type:	510(k) Exempt
Regulation Number:	862.1350
Reviewing Product Branch:	Office of In Vitro Diagnostics and Radiological Health (OIR)

III. PREDICATE DEVICE [907.92(a)(3)]

Dexcom Share Direct Secondary Displays, DEN140038

IV. DEVICE DESCRIPTION [807.92(a)(4)]

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)

V. INDICATIONS FOR USE [807.92(a)(5)]

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 is not intended to replace the real-time display of continuous glucose monitoring 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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The MiniMed Connect system has similar technological characteristics as the predicate device. The form, fit, function, and method of operation are similar.

VII. PERFORMANCE DATA [807.92(b)]

Results of the verification and validation testing indicate that the product meets established performance requirements, and is safe and effective for its intended use.

VIII. CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, the MiniMed Connect system, is substantially equivalent in its intended use, performance, safety, effectiveness, and the underlying scientific and operating principles used, to the predicate Dexcom Share Direct Secondary Displays.