



**U.S. FOOD & DRUG  
ADMINISTRATION**

March 8, 2018

Medtronic MiniMed  
Liane Miller, M.S.  
Regulatory Affairs Manager  
18000 Devonshire Street  
Northridge, California 91325-1219

Re: P160007

Trade/Device Name: Guardian Connect system

Filed: March 9, 2016

Amended: P160007/A001, April 20, 2016

P160007/A002, April 27, 2016

P160007/A003, May 17, 2016

P160007/A004, November 10, 2016

P160007/A005, February 21, 2017

P160007/A006, December 21, 2017

Product Code: MDS

Dear Ms. Miller:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Guardian Connect system. This device is indicated for the following:

The Guardian Connect system is indicated for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in patients (14 to 75 years of age) with diabetes mellitus.

The Guardian Connect system provides real-time glucose values and trends through a Guardian Connect app installed on a compatible consumer electronic mobile device. It allows users to detect trends and track patterns in glucose concentrations. The Guardian Connect app alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

The Guardian Connect system is comprised of the following devices: Guardian Connect app, Guardian Sensor (3), and the Guardian Connect transmitter.

**Guardian Sensor (3):**

The Guardian Sensor (3) is intended for use with Medtronic Diabetes glucose-sensing systems, to continuously monitor glucose levels in persons with diabetes. The Guardian Sensor (3) is indicated for 7 days of continuous use. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription.

**Guardian Connect Transmitter:**

The Guardian Connect transmitter is intended for use with the Guardian Connect system. The Guardian Connect transmitter powers the glucose sensor, collects and calculates sensor data, and sends the data via Bluetooth version 4.0 to the Guardian Connect app installed on a compatible mobile device. The transmitter is only compatible with the Guardian Sensor (3). The transmitter is indicated for multiple uses on a single patient as a component of the Guardian Connect system.

The Guardian Connect transmitter requires a prescription.

**Guardian Connect App:**

The Guardian Connect app is intended for use only by patients using a compatible mobile device, and who have sufficient experience to adjust mobile device audio and notification settings. The app displays sensor glucose data, and also provides a user interface for sensor calibration, entering data such as exercise and meals, and uploading information to the CareLink Personal website. It allows users to detect trends and track patterns in glucose concentrations. The Guardian Connect app provides alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values.

The Guardian Connect app is available over-the-counter (OTC) but requires the Guardian Sensor (3) and Guardian Connect transmitter to function.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for the Guardian Sensor (3) has been established and approved at 12 months at storage conditions between 36°F to 80°F. Expiration dating for the Guardian Connect transmitter has been established and approved at 6 months at storage conditions between -4°F to 131°F and up to 95% humidity with no condensation. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, <http://www.fda.gov/udi>.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes

aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
PMA Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Brittany Schuck at 301-796-5199 or [Brittany.Schuck@fda.hhs.gov](mailto:Brittany.Schuck@fda.hhs.gov).

Sincerely,

  
**Courtney H. Lias -S**

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