August 29, 2025

Medtronic Minimed, Inc.
Maria Hategan
Principal Regulatory Affairs Specialist
18000 Devonshire Street
Northridge, California 91325

Re: P160017/S124
Trade/Device Name: MiniMed 780G System
Product Code: OZP
Filed: April 25, 2025

Dear Maria Hategan:

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) supplement for the MiniMed 780G System for expanding the indications for use to include type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The device is indicated for the following:

MiniMed 780G System for use with Guardian 4 Sensor and Guardian 4 Transmitter

The MiniMed 780G system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The MiniMed 780G system consists of the following devices:

- MiniMed 780G insulin pump
- Guardian 4 transmitter
- Guardian 4 sensor
- One-press serter
- Accu-Chek Guide Link blood glucose meter
- Accu-Chek Guide Test Strips

The system requires a prescription from a healthcare professional.

Guardian 4 sensor

The Guardian 4 sensor is intended for use with the MiniMed 780G system and the Guardian 4 transmitter to monitor glucose levels for the management of diabetes.

The sensor is intended for single use and requires a prescription. The Guardian 4 sensor is indicated for up to seven days of continuous use.

The Guardian 4 sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucosemeter and not on values provided by the Guardian 4 sensor.

The Guardian 4 sensor has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table.

System	Age	Sensor Insertion Site
MiniMed 780G System	7 years and older	Arm

One-press Serter

The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use.

Guardian 4 transmitter

The Guardian 4 transmitter is intended for use with the MiniMed 780G system and Guardian 4 sensor to monitor glucose levels for the management of diabetes.

Accu-Chek Guide™ Link Blood Glucose Monitoring System

The Accu-Chek Guide Link Blood Glucose Monitoring system is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for *in-vitro* diagnostic single-patient use by people with diabetes. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to

wirelessly transmit glucose values to the MiniMed 780G system and MiniMed 770G system with Bluetooth wireless technology through the use of Bluetooth low energy communication.

MiniMed 780G System for use with Simplera Sync Sensor

The MiniMed 780G system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The MiniMed 780G system consists of the following devices:

- MiniMed 780G insulin pump
- Simplera Sync
- Accu-Chek™ Guide Link blood glucose meter
- Accu-Chek Guide Test Strips

The system requires a prescription from a healthcare professional.

Simplera Sync Sensor

The Simplera Sync sensor is intended for use with the MiniMed 780G system to monitor glucose levels for the management of diabetes. The Simplera Sync sensor can be used one time and has a life of up to six days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first six days, to allow the patient to change their sensor more flexibly. The Simplera Sync sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Simplera Sync sensor. The Simplera Sync sensor has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table.

System	Age	Sensor Insertion Site
MiniMed 780G	7 years and	Arm

Accu-Chek Guide Link Blood Glucose Monitoring System

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The Accu-Chek Guide Link Blood Glucose Monitoring System is

intended to be used to wirelessly transmit glucose values to the MiniMed 780G system and MiniMed 770G system with Bluetooth™ wireless technology through the use of Bluetooth low energy communication.

Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

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. In addition, the device is restricted under section 515(d)(1)(B)(ii) of the act in that the following statement must appear prominently and conspicuously in all advertising and promotional materials for this device, as well as prominently and conspicuously immediately following the Indications for Use statement in the Operators Manual that is to be distributed with the device:

WARNING: Do not use the SmartGuard feature for people who require less than eight units or more than 250 units of total daily insulin per day. A total daily dose of at least eight units, but no more than 250 units, is required to use the SmartGuard feature.

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 all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

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. 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 must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), 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.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (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 Part 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. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

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. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, 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 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

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 at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. 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 a copy 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, 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
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 Alexander Klonoff at Alexander.Klonoff@fda.hhs.gov.

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Director
Division of Chemistry and
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