



July 9, 2026

Medtronic MiniMed
Rushabh Patel
Principal Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 91325

Re: K261962

Trade/Device Name: SmartGuard Technology; Predictive Low Glucose Technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI, QJS, NDC
Dated: June 11, 2026
Received: June 11, 2026

Dear Rushabh Patel:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/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 (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


JOSHUA BALSAM -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

?

Please provide the device trade name(s).

?

SmartGuard Technology;
Predictive Low Glucose Technology

Please provide your Indications for Use below.

?

SmartGuard Technology:

SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.

SmartGuard technology is intended for the management of Type 1 diabetes mellitus in persons 7 years of age and older, and Type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

SmartGuard technology is intended for single patient use and requires a prescription.

Predictive Low Glucose Technology:

Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values.

Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data.

Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

Predictive Low Glucose technology is intended for single patient use and requires a prescription.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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Bundled 510(K) Summary

SmartGuard Technology and Predictive Low Glucose Technology

510(k) Submitter and Device Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Rushabh Patel Principal Regulatory Affairs Specialist Medtronic MiniMed Inc. rushabh.k.patel@medtronic.com
Alternate Contact Person	Siddhi Rasam Senior Regulatory Affairs Manager Medtronic MiniMed Inc. siddhi.rasam@medtronic.com
Device Trade Name	SmartGuard Technology, Predictive Low Glucose Technology
Device Common Name	Advanced Hybrid Closed Loop Algorithm, Predictive Low Glucose Management Algorithm
Device Classification Name	Interoperable Automated Glycemic Controller
Regulation Number	21 CFR 862.1356
Product Codes	QJI, QJS, NDC
Predicate Device	K253701- SmartGuard Technology and Predictive Low Glucose Technology
Device Panel	Clinical Chemistry
Device Class	Class II

Device Description for SmartGuard Technology

SmartGuard Technology, also referred to as the Advanced Hybrid Closed Loop (AHCL) algorithm, is a software-only interoperable automated glycemic controller (iAGC) intended to adjust basal insulin delivery and perform automatic correction boluses based on user-entered inputs and sensor glucose (SG) values obtained from a compatible integrated continuous glucose monitor (iCGM) or an interoperable Medtronic MiniMed continuous glucose monitor (CGM).

SmartGuard Technology is embedded within the firmware of a compatible alternate controller enabled (ACE) pump, which functions as the host device.

The ACE pump receives SG data from compatible CGM/iCGM devices via Bluetooth Low Energy (BLE) and also collects user inputs through the ACE pump (for pumps that have a screen) or the MiniMed App (for screenless pumps). The AHCL algorithm does not directly communicate with CGMs/iCGMs; instead, the ACE pump transmits CGM/iCGM data and user-entered inputs to the AHCL algorithm and receives the algorithm's output commands.

In SmartGuard Mode, the AHCL algorithm uses adaptive control to adjust insulin delivery every five (5) minutes based on SG values. It delivers an auto basal insulin dose to maintain user-selectable targets of 100, 110, or 120 mg/dL, supports a temporary target of 150 mg/dL for up to 24 hours, and can automatically deliver correction boluses when appropriate.

Meal boluses are the responsibility of the user. The AHCL algorithm includes an integrated bolus calculator that determines user-initiated meal bolus doses based on available SG information, carbohydrate input, and other patient parameters.

The AHCL algorithm is a software-only device with no user interface. All therapy settings, user interactions, and AHCL-related alerts or alarms are managed through the compatible ACE pump or the MiniMed App. An optional App Manager device with the MiniMed App pre-installed is available as an alternative to a user's personal mobile device.

Indications for Use / Intended Use for SmartGuard Technology

SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.

SmartGuard technology is intended for the management of Type 1 diabetes mellitus in persons 7 years of age and older, and Type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

SmartGuard technology is intended for single patient use and requires a prescription.

Device Description for Predictive Low Glucose Technology

Predictive Low Glucose Technology, also referred to as the Predictive Low Glucose Management (PLGM) algorithm, is a software-only interoperable automated glycemic controller (iAGC) that is intended to automatically suspend delivery of insulin when sensor glucose (SG) values fall below or are predicted to fall below predefined threshold values based on user-entered inputs. The PLGM algorithm is embedded within the firmware of a compatible alternate controller enabled (ACE) pump, which functions as the host device.

The ACE pump receives SG data from a compatible integrated continuous glucose monitor (iCGM) or interoperable Medtronic MiniMed CGM via Bluetooth Low Energy (BLE) and collects user-entered inputs through the ACE pump (for pumps that have a screen) or the MiniMed App (for screenless pumps). The PLGM algorithm does not directly communicate with CGM/iCGM devices; instead, the ACE pump transmits CGM/iCGM data and user inputs to the algorithm and receives the resulting suspend and resume commands. PLGM functionality is available only in Manual mode. In this mode, users are responsible for all basal and bolus insulin delivery, including user-defined basal rate patterns and user-initiated boluses, with optional use of the bolus calculator and the max bolus limit feature. When enabled, the PLGM algorithm may suspend insulin delivery for a minimum of 30 minutes and up to 2 hours based on current or predicted SG values and will automatically resume delivery when criteria are met or when the maximum suspend duration is reached. Users may also manually resume delivery at any time.

The PLGM algorithm is a software-only device with no user interface. All therapy settings, user interactions, and PLGM-related alerts or alarms are managed through the compatible ACE pump or the MiniMed App. An optional App Manager device with the MiniMed App pre-installed is available as an alternative to a user's personal mobile device.

Indications for Use / Intended Use for Predictive Low Glucose Technology

Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values.

Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data.

Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

Predictive Low Glucose technology is intended for single patient use and requires a prescription.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The table below provides a side-by-side comparison of the subject device, **SmartGuard Technology**, compared to its predicate device for Product Code **QJI**.

	Predicate Device SmartGuard Technology (Advanced Hybrid Closed Loop (AHCL) Algorithm) (K253701)	Subject Device SmartGuard Technology (Advanced Hybrid Closed Loop (AHCL) Algorithm)
Manufacturer	Medtronic MiniMed Inc.	SAME
Device Trade Name	SmartGuard Technology	SAME
Device Classification	Class II	SAME
Product Code	QJI	SAME
Regulation Name	Interoperable Automated Glycemic Controller (under 21 CFR 862.1356)	SAME
Indications For Use/Intended Use	SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values. SmartGuard technology is intended for the management of Type 1 diabetes mellitus in persons 7 years of age and older, and Type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. SmartGuard technology is intended for single patient use and requires a prescription.	SAME
Prescription Use	Prescription is required	SAME

Environment Of Use	Professional healthcare facilities and home environments	SAME
Intended Population	Type 1 diabetes mellitus in persons 7 years of age and greater. Type 2 diabetes mellitus in persons 18 years of age and greater ¹	SAME
Principal Operator	Patient or caregiver	SAME
Number Of Users	Single user	SAME
Principle Of Operation	Algorithmic software device intended to automatically increase, decrease, and suspend delivery of insulin based on current and trending CGM values, insulin delivery history and user input.	SAME
Specific Drug/Biological Use	U-100 insulin: ² Novolog® Humalog® Admelog® Fiasp® Lyumjev®	SAME
Total Daily Dose (TDD) Of Insulin	8 to 250 units a day	SAME
Active Insulin Time	User adjustable (between 2 - 8 hours)	SAME
Insulin Adjustment	AHCL algorithm can be used to manage Bolus and Basal rate every 5 minute interval.	SAME
Glucose Target (Target Settings)	Glucose Targets (Target Setpoint): • 100 mg/dL • 110 mg/dL • 120 mg/dL Temp Target: 150 mg/dL	SAME
Auto Correction Bolus Target	120 mg/dL	SAME

The table below provides a side-by-side comparison of the subject device, **Predictive Low Glucose Technology**, compared to its predicate device for Product Code **QJS**.

	Predicate Device Predictive Low Glucose Technology (Predictive Low Glucose Management (PLGM) Algorithm)	Subject Device Predictive Low Glucose Technology (Predictive Low Glucose Management (PLGM) Algorithm)
Manufacturer	Medtronic MiniMed Inc.	SAME
Device Trade Name	Predictive Low Glucose Technology	SAME
Device Classification	Class II	SAME

¹ SmartGuard Technology for the management of Type 2 diabetes was cleared under K253585.

² The use of Lyumjev and Fiasp insulins was cleared under K253470.

Product Code	QJS	SAME
Regulation Name	Interoperable automated glycemic controller, insulin suspend (under 21 CFR 862.1356)	SAME
Indications For Use/Intended Use	Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values. Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data. Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. Predictive Low Glucose technology is intended for single patient use and requires a prescription.	SAME
Prescription Use	Prescription is required	SAME
Environment Of Use	Professional healthcare facilities and home environments	SAME
Intended Population	Type 1 diabetes mellitus in persons 7 years of age and greater. Type 2 diabetes mellitus in persons 18 years of age and greater. ³	SAME
Number Of Users	Single user	SAME
Principle Of Operation	Algorithmic software device that utilizes CGM sensor readings to stop and resume insulin based on the current and predicted (30 minutes into the future) sensor values.	SAME
Specific Drug/Biological Use	U-100 insulin: ⁴ Novolog® Humalog® Admelog®	SAME

³ Predictive Low Glucose technology for the management of Type 2 diabetes was cleared under K253585.

⁴ The use of Lyumjev and Fiasp insulins was cleared under K253470

	Fiasp® Lyumjev®	
Can Automatically Resume Insulin Delivery	Yes	SAME
Basal Insulin Delivery Suspension	Suspend on Low: Based on the current CGM value is less than or equal to the low limit (50 to 90 mg/dL). Suspend before Low: Based on 30 minute predictive CGM value is less than equal to low limit (50 to 90 mg/dL) and current sensor glucose values.	SAME
Bolus Insulin Delivery Suspension	Any ongoing bolus delivery will be cancelled.	SAME
	Minimum – 30 minutes Maximum - 2 hours User can resume delivery at any time	SAME

The table below provides a side-by-side comparison of the subject device, **Predictive Low Glucose Technology**, compared to its predicate device for Product Code NDC.

	Predicate Device Predictive Low Glucose Technology (Predictive Low Glucose Management (PLGM))	Subject Device Predictive Low Glucose Technology (Predictive Low Glucose Management (PLGM) Algorithm)
Manufacturer	Medtronic MiniMed Inc.	SAME
Device Trade Name	Predictive Low Glucose Technology	SAME
Device Type	Predictive Pulmonary-Function Value Calculator (21 CFR 868.1890)	SAME
Device Classification	Class II	SAME
Product Code	NDC	SAME
Indications for Use/Intended Use	Predictive Low Glucose technology contains a bolus calculator that calculates an insulin dose based on user-entered data.	SAME
Therapy Type	Diabetes patients treated with insulin pump therapy in which calculator is integrated	SAME
Specific Drug/Biological Use	U-100 insulins	SAME

Principles of Operation	Calculate insulin doses for meals and corrections while accounting for active insulin (insulin on board).	SAME
Carbohydrate Calculator	Calculates carbohydrate intake based on user-entered data.	SAME
Manual Data Entry	Yes	SAME
Requires BG for calculation	Yes	SAME

Special Controls

Evaluation and adherence to the Special Controls of the Predicate Device (K253701) demonstrates continued assurance of the safety and effectiveness of the Subject Devices.

Interoperability

Interoperability documentation was provided in accordance with FDA Guidance “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” (September 2017) and the requirements defined by the iAGC special controls in 21 CFR 862.1356.

Pre-determined Change Control Plan (PCCP)

An updated pre-determined change control plan (PCCP) for planned modifications to the SmartGuard Technology and Predictive Low Glucose Technology was provided in accordance with the FDA Draft Guidance, “*Predetermined Change Control Plans for Medical Devices*” (August 2024). It included modifications for integrating with potential interoperable devices in the future. The PCCP included a description of modifications, a modification protocol, traceability from modifications to the modification protocols and an impact assessment.

Conclusion

The subject devices, SmartGuard Technology and Predictive Low Glucose Technology do not raise new safety or effectiveness questions as they have the same intended use, same indications for use, and operate in the same environment as their respective predicate devices. Based on side-by-side comparison of the subject devices and predicate device have been shown to be substantially equivalent.