January 14, 2026

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

Re: K253585
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
Dated: November 17, 2025
Received: November 17, 2025

Dear Maria Hategan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k253585

Device Name
SmartGuard technology

Indications for Use *(Describe)*
SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGMs), and alternate controller enabled (ACE) pumps to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose values.

SmartGuard technology is intended 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 olderrequiring insulin.

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k253585

Device Name
Predictive Low Glucose technology

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

Predictive Low Glucose technology is intended 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.

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

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.

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Bundled 510(k) Summary
SmartGuard Technology and Predictive Low Glucose Technology

510(k) Submitter Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Maria Hategan Principal Regulatory Affairs Specialist Medtronic MiniMed Inc. Email: maria.hategan@medtronic.com
Alternate Contact Person	Felicia Haynes, PhD Senior Regulatory Affairs Manager Medtronic MiniMed Inc. Email: felicia.a.haynes@medtronic.com
Date Prepared	November 14, 2025

Device Information

Device Trade Name	SmartGuard technology, Predictive Low Glucose technology
Device Common Name	Advanced Hybrid Closed Loop (AHCL) algorithm, Predictive Low Glucose Management (PLGM) algorithm
Device Classification Name	Interoperable Automated Glycemic Controller (iAGC)
Regulation Number	21 CFR 862.1356
Product Code	QJI, QJS
Device Panel	Clinical Chemistry
Device Class	Class II

Predicate Device Information

Product Code	**Predicate Device**
QJI	SmartGuard technology (**K251217**)
QJS	Predictive Low Glucose technology (**K251217**)

Device Description

SmartGuard technology

SmartGuard technology, also referred to as **Advanced Hybrid Closed Loop (AHCL) algorithm**, is a software-only device intended for use by people with Type 1 diabetes, ages 7 years or older, and by people with Type 2 diabetes, ages 18 years or older. It is an interoperable automated glycemic controller (iAGC) that is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible interoperable Medtronic continuous glucose monitors (CGM) and compatible alternate controller enabled (ACE) pumps to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.

The AHCL algorithm resides on the compatible ACE pump, which serves as the host device. It is meant to be integrated in a compatible ACE pump and is an embedded part of the ACE pump firmware.

Inputs to the AHCL algorithm (e.g., SG values, user inputs) are received from the ACE pump (host device), and outputs from the AHCL algorithm (e.g., insulin delivery commands) are sent by the algorithm to the ACE pump. As an embedded part of the firmware, the AHCL algorithm does not connect to or receive data from compatible CGMs; instead, sensor glucose (SG) values or other inputs received by the ACE pump from compatible CGMs via Bluetooth Low Energy (BLE) technology are transmitted to the embedded AHCL algorithm.

The AHCL algorithm works in conjunction with the ACE pump and is responsible for controlling insulin delivery when the ACE pump is in Auto Mode. It includes adaptive control algorithms that autonomously and continually adapt to the ever-changing insulin requirements of each individual.

The AHCL algorithm requires specific therapy settings (target setpoint, insulin-to-carb ratios and active insulin time) that need to be established with the help of a health care provider (HCP) before activation. It also requires five (5) consecutive hours of insulin delivery history, a minimum of two (2) days of total daily dose (TDD) of insulin, a valid sensor glucose (SG) and blood glucose (BG) values to start automated insulin delivery.

When activated, the AHCL algorithm adjusts the insulin dose at five-minute intervals based on CGM data. A **basal insulin dose (auto basal)** is commanded by the AHCL algorithm to manage glucose levels to the user's target setpoint of 100 mg/dL, 110 mg/dL or 120 mg/dL. The user can

also set a temporary target of 150 mg/dL for up to 24 hours. In addition, under certain conditions the algorithm can also automatically command **correction boluses (auto correction bolus)** without user input.

Meal boluses are the responsibility of the user. The AHCL algorithm includes an integrated bolus calculation feature for user-initiated boluses for meals. When the user inputs their carbohydrate intake, the AHCL algorithm automatically calculates a bolus amount based off available glucose information, entered carbohydrate amount and other patient parameters.

The AHCL algorithm contains several layers of "safeguards" (mitigations) to provide protection against over-delivery or under-delivery of insulin to reduce risk of hypoglycemia and hyperglycemia, respectively.

The AHCL algorithm is a software-only device and does not have a user interface (UI). The compatible ACE pump provides a UI to the user to configure the therapy settings and interact with the algorithm. The AHCL-related alerts/alarms are displayed and managed by the pump.

Predictive Low Glucose technology

Predictive Low Glucose technology, also referred to as the **Predictive Low Glucose Management (PLGM) algorithm** is a software-only device intended for use by people with Type 1 diabetes, ages 7 years or older, and by people with Type 2 diabetes, ages 18 years or older. It is an interoperable automated glycemic controller (iAGC) that is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible interoperable Medtronic continuous glucose monitors (CGM) and compatible alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

The PLGM algorithm resides on the compatible ACE Pump, which serves as the host device. It is meant to be integrated in a compatible ACE pump and is an embedded part of the ACE pump firmware.

Inputs to PLGM algorithm (e.g., sensor glucose values, user inputs) are received from the ACE pump (host device), and outputs from PLGM algorithm (e.g., suspend/resume commands) are sent by the algorithm to the ACE pump. As an embedded part of the ACE pump firmware, the PLGM algorithm does not connect to or receive data from compatible CGMs; instead, sensor glucose (SG) values or other inputs are received by the ACE pump from compatible CGMs via Bluetooth Low Energy (BLE) technology are transmitted to the embedded PLGM algorithm.

The PLGM algorithm works in conjunction with the ACE pump. When enabled, the PLGM algorithm is able to suspend insulin delivery for a minimum of 30 minutes and for a maximum of 2 hours based on current or predicted sensor glucose values. It will automatically resume insulin delivery when maximum suspend time of 2 hours has elapsed or when underlying conditions resolve. The user is also able to manually resume insulin at any time.

The PLGM algorithm is a software-only device and does not have a user interface (UI). The compatible ACE pump provides the UI to configure therapy settings and interact with the algorithm. The PLGM-related alerts/alarms are displayed and managed by the pump.

Indications for Use / Intended Use

SmartGuard technology

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

SmartGuard technology is intended 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.

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 (CGMs), and alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

Predictive Low Glucose technology is intended 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.

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

Summary of Technological Characteristics – Subject Device Compared to Predicate Device

SmartGuard technology [Product Code: QJI]

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

	Subject Device **SmartGuard technology** **(Advanced Hybrid Closed Loop algorithm)**	**Predicate Device** **SmartGuard technology** **(K251217)**
Manufacturer	Medtronic MiniMed Inc.	Medtronic MiniMed Inc.
Device Trade Name	SmartGuard technology	SmartGuard technology
Device Classification	Class II	**SAME**
Regulation Name	Interoperable Automated Glycemic Controller (under 21 CFR 862.1356)	**SAME**
Intended Use	SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), and alternate controller enabled (ACE) pumps to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose values. SmartGuard technology is intended for single patient use and requires a prescription.	**SAME**
Prescription Use	Prescription is required	**SAME**
Clinical Application	Type 1 and Type 2 diabetes mellitus	Type 1 diabetes mellitus
Intended Population	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.	Type 1 diabetes mellitus in persons 7 years of age and greater.
Principal Operator	Patient or caregiver	**SAME**
Number Of Users	Single user	**SAME**
Principle Of Operation	Algorithmic software device intended to automatically increase, decrease, suspend and resume delivery of insulin based on sensor glucose values	**SAME**
Compatible Host device/Hardware	ACE Pump	**SAME**

	Subject Device **SmartGuard technology** **(Advanced Hybrid Closed Loop algorithm)**	**Predicate Device** **SmartGuard technology** **(K251217)**
Compatible CGM	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Medtronic Continuous Glucose Monitors (CGMs)	**SAME**
Communication With ACE Pump	Communicates with an ACE Pump via software interface	**SAME**
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog® Admelog® Lyumjev® Fiasp®	U-100 insulin: Novolog® Humalog® Admelog®
Total Daily Dose (TDD) Of Insulin	8 to 250 units a day	**SAME**
Active Insulin Time	User adjustable (between 2 - 8 hours)	**SAME**
Basal Insulin Adjustment	AHCL algorithm can be used to adjust or suspend basal insulin delivery every 5 minutes and automatically deliver correction boluses based on current and trending CGM values, target setpoint and insulin delivery history.	**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 Basal Operating Modes	AHCL algorithm does not have separate auto basal operating modes. The default mode is auto basal (which includes setting a temporary target). AHCL algorithm can transition to a set limited basal delivery rate should conditions arise.	**SAME**
Auto Correction Bolus Target	120 mg/dL	**SAME**
Auto Correction Bolus Rate	Calculated at 5-minute intervals	**SAME**
Meal / Food Bolus	Users must manually deliver meal boluses they can calculate using the integrated bolus calculator. An SG or BG value is used for meal boluses.	**SAME**
Manual Algorithm Deactivation	Users can manually turn off closed loop therapy	**SAME**

	Subject Device **SmartGuard technology** **(Advanced Hybrid Closed Loop algorithm)**	**Predicate Device** **SmartGuard technology** **(K251217)**
Auto Mode Exit	Algorithm automatically de-activates and exits auto mode when conditions arise.	**SAME**
Alarms/Alerts	ACE pump will display algorithm-related alerts to the user	**SAME**
Mechanism Of Software Update	Firmware over the Air	**SAME**
Training	There is mandatory user training before the user can use AHCL Algorithm	**SAME**

Predictive Low Glucose technology [Product Code: QJS]

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

	Subject Device **Predictive Low Glucose technology** **(Predictive Low Glucose Management algorithm)**	**Predicate Device** **Predictive Low Glucose technology** **(K251217)**
Manufacturer	Medtronic MiniMed Inc.	Medtronic MiniMed Inc.
Device Trade Name	Predictive Low Glucose technology	Predictive Low Glucose technology
Device Classification	Class II	**SAME**
Regulation Name	Interoperable automated glycemic controller (under 21 CFR 862.1356)	**SAME**
Intended Use	Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM) and alternate controller enabled (ACE) pumps to automatically suspend delivery of insulin when the sensor glucose value is predicted to fall below predefined threshold values. Predictive Low Glucose technology is intended for single patient use and requires a prescription.	**SAME**
Prescription Use	Prescription is required	**SAME**
Clinical Application	Type 1 and Type 2 diabetes mellitus	Type 1 diabetes mellitus
Intended Population	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.	Type 1 diabetes mellitus in persons 7 years of age and greater.
Number Of Users	Single user	**SAME**
Principle Of Operation	Algorithmic software device that utilizes CGM sensor readings to suspend and resume insulin based on the current and predicted sensor values.	**SAME**
Compatible Host Device / Intended Hardware	ACE Pump	**SAME**
Compatible CGM	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Medtronic Continuous Glucose Monitors (CGMs)	**SAME**
Communication With ACE Pump	Communicates with an ACE Pump via software interface	**SAME**

	Subject Device **Predictive Low Glucose technology** **(Predictive Low Glucose Management algorithm)**	**Predicate Device** **Predictive Low Glucose technology** **(K251217)**
Specific Drug/Biological Use	U-100 insulin: Novolog® Lyumjev® Humalog® Fiasp® Admelog®	U-100 insulin: Novolog® Humalog® Admelog®
Commands Suspension of Insulin Delivery Based On Current and Predicted CGM Values	Yes	**SAME**
Manual Bolus during Suspension	A new bolus cannot be initiated until insulin delivery is resumed	**SAME**
Manual Algorithm Deactivation	User can manually turn off the therapy/algorithm	**SAME**
Alarms/Alerts	ACE pump will display algorithm-related alerts to the user	**SAME**
Mechanism Of Software Update	Firmware over the Air	**SAME**
Training	There is mandatory user training before the user can use the PLGM algorithm	**SAME**

Summary of Non-Clinical Performance Data

Medtronic conducted performance testing for SmartGuard technology (AHCL algorithm) and Predictive Low Glucose technology (PLGM algorithm), collectively referred to as "Medtronic iAGCs", to demonstrate substantial equivalence to the predicate device(s) and to ensure that the subject device(s) (Medtronic iAGCs) meets all applicable iAGC Special Controls requirements defined in 21 CFR 862.1356. These are summarized below:

Software Verification and Validation

Software Verification activities were performed in accordance with IEC 62304 and FDA's 2023 guidance "*Content of Premarket Submissions for Device Software Functions*".

Data Logging

Medtronic iAGCs with compatible ACE pump have been verified for logging or recording timestamped critical events as required by the special controls.

Cybersecurity

The cybersecurity activities for the Medtronic iAGCs were all completed per cybersecurity plan and cybersecurity risks were assessed for impact to confidentiality, integrity, and availability. A robust cybersecurity risk assessment was conducted, all cybersecurity risks with potential to impact safety were mitigated. The information relating to the penetration testing conducted and software bill of materials was provided.

Human Factors Validation

A human factors and usability engineering process was performed on Medtronic iAGCs integrated with the compatible ACE pump and paired with a compatible CGM, in accordance with IEC 62366-1:2015, HE75:2009 and FDA's guidance document, *Applying Human Factors and Usability Engineering to Medical Devices (February 2016)*. Results of the human factors validation testing demonstrated that the device is safe and effective for the intended users, intended uses and expected tasks, and intended use environments.

Labeling and Training

Medtronic iAGCs' labeling and training for users and healthcare practitioners is sufficient and satisfies applicable requirements of 21 CFR 801.

Other Supportive Test Data:

The following additional testing was conducted, per currently authorized PCCP:

- Qualification and Integration of iAGCs with compatible new ACE Pump, SW v6.60
- Qualification and Integration of iAGCs with compatible iCGM (Instinct, made by Abbott)

The following tests are not applicable to Medtronic iAGCs as they are software-only devices – *Analytical Performance, Biocompatibility, Sterility, Insulin Compatibility and Stability, Electrical Safety, EMC/EMI and RF Wireless, CGM connectivity, Reliability and Shelf Life, Packaging/ Shipping Integrity and Mechanical Tests*.

Risk Management

Risk management was completed in accordance with ISO 14971: 2019. Risk control measures identified for each hazard were implemented and verified to be effective at reducing risk, Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met, and the device is safe for use. All risks have been reduced as far as possible. The benefit risk analysis has determined that the benefits of using the device outweigh the residual risk, and the overall residual risk is acceptable.

Summary of Clinical Performance Data for SmartGuard Technology and Predictive Low Glucose Technology

Clinical Testing for SmartGuard Technology (AHCL Algorithm)

AHCL with Simplera Sync CGM (Type 1 Diabetes) – provided in K251217

Safety and effectiveness evaluation of the AHCL algorithm in the MiniMed 780G System used in combination with the Simplera Sync CGM (in Type 1 Diabetes patients) was reviewed in **K251217**.

The pivotal clinical data provided in **K251217** confirmed the safety and effectiveness of the modified iAGC AHCL algorithm) integrated in the compatible ACE Pump (MiniMed 780G ACE pump) used in combination with the compatible interoperable Simplera Sync sensor in patients with type 1 diabetes. The study demonstrated improved glycemic outcomes (reduction in HbA1c) compared to baseline, superiority for time in range and non-inferiority for reduction HbA1c.

AHCL with Simplera Sync CGM (Type 2 Diabetes) – provided in this submission [approved in P160017/S124]

Safety and effectiveness of the MiniMed 780G System used in combination with Simplera Sync CGM and Guardian 4 CGM in adults with insulin-requiring Type 2 Diabetes is provided in this submission to support an indication expansion for MiniMed 780G system use in Type 2 (also approved under **P160017/S124**).

This study was a multi-center, single arm study in insulin-requiring adults with type 2 diabetes, conducted in two phases. The study phases used two versions of the MiniMed 780G insulin pump (Phase 1 – AHCL and Phase 2 – modified AHCL) with two different CGMs (Phase 1 – Guardian 4 CGM, Phase 2 – DS5 Simplera Sync sensor).

The demographic of subjects of the intended-to-treat population (ITT) enrolled in Phase 1 of the study (MiniMed 780G with Guardian 4 CGM) and in Phase 2 of the study (MiniMed 780G with Simplera Sync sensor) are presented in the tables below.

Summary of Demographic and Other Baseline Characteristics, ITT Population (Phase 1)

Characteristic	Number of Subjects=95
Age (Years)	
n	95
Mean (SD)	60.3 (10.8)

Characteristic	Number of Subjects=95
Median	62.0
Min, Max	27.0, 80.0
Gender, N (%)	
Female	47 (49.5%)
Male	48 (50.5%)
Race, N (%)	
White	76 (80.0%)
Black or African American	16 (16.8%)
Asian	2 (2.1%)
Asian/White	1 (1.1%)
Ethnicity, N (%)	
Hispanic Or Latino	5 (5.3%)
Not Hispanic Or Latino	89 (93.7%)
Not Reported	1 (1.1%)
Baseline Therapy, N (%)	
Closed Loop Therapy (Pump + CGM + Algorithm)	7 (7.4%)
CSII	9 (9.5%)
Injection	58 (61.1%)
Other	2 (2.1%)
SAP (Pump + CGM)	19 (20.0%)
Diabetes History (Years)	
n	95
Mean (SD)	18.6 (8.6)
Median	19.8
Min, Max	3.3, 43.1
Height (cm)	
n	95
Mean (SD)	171.6 (8.8)
Median	170.2
Min, Max	153.7, 198.1
Weight (kg)	
n	95
Mean (SD)	105.8 (21.8)
Median	103.1
Min, Max	66.3, 192.8
BMI (kg/m^2)	
n	95
Mean (SD)	36.0 (7.4)
Median	35.2
Min, Max	21.4, 68.6
Baseline HbA1C (%)	
n	95
Mean (SD)	7.9 (1.0)
Median	7.9
Min, Max	5.5, 9.8

Summary of Demographic and Other Baseline Characteristics, ITT Population (Phase 2)

Characteristic	Combined* Number of Subjects = 302	Transition Number of Subjects = 66	Naïve Number of Subjects = 236
Age (Years)			
n	302	66	236
Mean (SD)	60.3 (11.3)	62.6 (11.2)	59.7 (11.2)
Median	61.5	64.0	61.0
Min, Max	24.0, 82.0	28.0, 82.0	24.0, 80.0
Gender, N (%)			
Female	168 (55.6%)	30 (45.5%)	138 (58.5%)
Male	134 (44.4%)	36 (54.5%)	98 (41.5%)
Race, N (%)			
American Indian or Alaska Native	2 (0.7%)	N/A	2 (0.8%)
American Indian or Alaska Native, White	1 (0.3%)	N/A	1 (0.4%)
Asian	18 (6.0%)	1 (1.5%)	17 (7.2%)
Asian, Black or African American	1 (0.3%)	N/A	1 (0.4%)
Asian, White	1 (0.3%)	N/A	1 (0.4%)
Black or African American	38 (12.6%)	8 (12.1%)	30 (12.7%)
Native Hawaiian / Other Pacific Islander	1 (0.3%)	N/A	1 (0.4%)
Not reported	4 (1.3%)	2 (3.0%)	2 (0.8%)
Other (Detribalized indigenous)	1 (0.3%)	N/A	1 (0.4%)
Other (Hispanic)	1 (0.3%)	N/A	1 (0.4%)
Other (Persian)	1 (0.3%)	N/A	1 (0.4%)
Other (White / Native American)	1 (0.3%)	N/A	1 (0.4%)
Other (Hispanic)	1 (0.3%)	N/A	1 (0.4%)
Unknown	2 (0.7%)	N/A	2 (0.8%)
White	229 (75.8%)	55 (83.3%)	174 (73.7%)
Ethnicity, N (%)			
Hispanic or Latino	44 (14.6%)	4 (6.1%)	40 (16.9%)
Not Hispanic or Latino	256 (84.8%)	62 (93.9%)	194 (82.2%)
Not Reported	1 (0.3%)	N/A	1 (0.4%)
Unknown	1 (0.3%)	N/A	1 (0.4%)
Diabetes History (Years)			
n	302	66	236
Mean (SD)	19.4 (9.6)	20.1 (9.1)	19.2 (9.7)
Median	19.0	20.5	18.6
Min, Max	2.4, 60.4	4.2, 44.7	2.4, 60.4
Baseline Height (cm)			
n	301	66	235
Mean (SD)	170.2 (9.9)	172.5 (8.8)	169.6 (10.1)
Median	170.2	170.7	170.0
Min, Max	147.3, 198.1	157.2, 198.1	147.3, 198.1
Baseline Weight (kg)			
n	301	66	235
Mean (SD)	100.5 (23.6)	109.4 (24.1)	98.0 (22.8)
Median	98.6	105.2	96.1
Min, Max	50.4, 204.2	64.7, 204.2	50.4, 178.7
Baseline BMI (kg/m^2)			

Characteristic	Combined* Number of Subjects = 302	Transition Number of Subjects = 66	Naïve Number of Subjects = 236
n	301	66	235
Mean (SD)	34.7 (7.7)	36.9 (8.5)	34.0 (7.3)
Median	33.5	35.3	32.9
Min, Max	20.3, 72.7	23.4, 72.7	20.3, 67.6
Baseline Therapy, N(%)			
Closed Loop Therapy (Pump+CGM+Algorithm)	66 (21.9%)	58 (87.9%)	8 (3.4%)
CSII	7 (2.3%)	N/A	7 (3.0%)
Injection	191 (63.2%)	1 (1.5%)	190 (80.5%)
Other	2 (0.7%)	N/A	2 (0.8%)
Sap (Pump + CGM)	36 (11.9%)	7 (10.6%)	29 (12.3%)
Baseline A1C (%)			
n	302	66	236
Mean (SD)	7.6 (0.9)	7.1 (0.7)	7.7 (0.9)
Median	7.5	6.9	7.7
Min, Max	5.6, 9.9	5.9, 9.0	5.6, 9.9

* The Combined subjects group included both Naïve and Transition subjects.

The pivotal clinical data (T2D) confirmed the safety and effectiveness of the MiniMed 780G system with Guardian 4 Sensor (Phase 1) and of the MiniMed 780G (modified AHCL) system with Simplera Sync Sensor (Phase 2), and use of AHCL SmartGuard was associated with improved glucose control in adult patients with insulin-requiring T2D. There were no reported device-related serious adverse events. In the target range of 70 to 180 mg/dL, a significant TIR of 80.9% of SG values was observed in Phase 1 and a TIR of 85.4% of SG values in Phase 2

AHCL with Guardian 4 CGM and Insulins (Type 1 Diabetes) – provided in this submission [approved under P160017/S125]

Safety and effectiveness of the MiniMed 780G System in combination with Guardian 4 CGM used in Type 1 Diabetes utilizing Lyumjev and Fiasp insulins is provided in this submission to support the use of additional insulins (also reviewed in **P160017/S125**).

AHCL with Guardian 4 and Lyumjev insulin

The study using Lyumjev® insulin lispro-aabc in the MiniMed 780G system was a single-arm, multi-center, home clinical investigation in insulin-requiring adult and pediatric subjects with type 1 diabetes. Altogether, the run-in period and study period were approximately 120 days long.

The baseline demographics of subjects 7–80 years of age that entered the study period for Lyumjev with SmartGuard (i.e. ITT population) are presented below.

Summary of Subject Demographic and Other Baseline (at Screening) Characteristics, ITT Population

Characteristic	Age 7-17 Years (N=101)	Age 18-80 Years (N=110)
Age (Years)		
Number of subjects, N	101	110
Mean (SD)	13.0 (2.6)	45.0 (14.2)
Median	13.0	45.5
Min, Max	8.0, 17.0	18.0, 75.0
Gender N (%)		
Female	51 (50.5%)	49 (44.5%)
Male	50 (49.5%)	61 (55.5%)
Race N (%)		
White	85 (84.2%)	103 (93.6%)
American Indian or Alaska Native, Asian, Black or African American	0 (0.0%)	1 (0.9%)
Black or African American	8 (7.9%)	4 (3.6%)
Asian, White	1 (1.0%)	0 (0.0%)
Asian	2 (2.0%)	0 (0.0%)
Native Hawaiian or Other Pacific Islander	1 (1.0%)	0 (0.0%)
Other, Mediterranean	0 (0.0%)	1 (0.9%)
Unknown	1 (1.0%)	0 (0.0%)
Not Reported	3 (3.0%)	1 (0.9%)
Ethnicity N (%)		
Hispanic or Latino	19 (18.8%)	7 (6.4%)
Not Hispanic or Latino	81 (80.2%)	103 (93.6%)
Not Reported	1 (1.0%)	0 (0.0%)
Diabetes History (Years)		
Number of subjects, N	101	110
Mean (SD)	6.1 (3.8)	26.9 (12.0)
Median	5.4	25.8
Min, Max	1.1, 17.2	2.6, 59.6
Height(cm)		
Number of subjects, N	101	110
Mean (SD)	157.2 (15.8)	173.5 (10.3)
Median	157.7	172.0
Min, Max	103.0, 186.6	149.0, 200.7
Weight (kg)		
Number of subjects, N	101	110
Mean (SD)	55.7 (17.5)	87.0 (19.4)
Median	55.6	83.9
Min, Max	20.0, 116.5	52.4, 135.4
Body Mass Index (kg/m^2)		
Number of subjects, N	101	110
Mean (SD)	22.0 (4.6)	28.8 (5.3)
Median	21.4	28.1
Min, Max	14.5, 41.6	15.9, 45.3
Treatment Method at Baseline N (%)		
Closed Loop Therapy (Pump + CGM + Algorithm)	85 (84.2%)	73 (66.4%)
CSII	2 (2.0%)	12 (10.9%)
Injection	0 (0.0%)	1 (0.9%)

Characteristic	Age 7-17 Years (N=101)	Age 18-80 Years (N=110)
Sap (Pump + CGM)	14 (13.9%)	24 (21.8%)
Baseline A1C (%)		
Number of subjects, N	101	110
Mean (SD)	7.6 (1.1)	7.4 (0.9)
Median	7.6	7.3
Min, Max	5.4, 9.8	5.8, 9.8

For subjects 7-17 years of age, Lyumjev insulin lispro-aabc was used with the MiniMed 780G system and the Guardian 4 continuous glucose monitor (CGM) during the Study Period with no reported serious adverse events.

For subjects 18-80 years of age, Lyumjev insulin lispro-aabc was used with the MiniMed 780G system and the Guardian 4 CGM during the Study Period. One non-device related serious adverse event was reported during the Screening period. No serious adverse events were reported during the run-in period when subjects used the system in either Manual Mode or with SmartGuard with Auto Correction turned off, or during the Study Period when subjects used the system in SmartGuard with Lyumjev.

The pivotal clinical data with Lyumjev (provided in **P160017/S125** and in this submission) confirmed the safety and effectiveness of the Lyumjev insulin lispro-aabc when used in combination with the MiniMed 780G system. The results also confirm that use of Lyumjev with the MiniMed 780G Auto Correction feature was associated with improved glucose control in all age groups.

AHCL with Guardian 4 and Fiasp insulin

The study using Fiasp (insulin aspart), faster-acting insulin injection with the MiniMed 780G system was a global multi-center, single arm study in insulin-requiring adult and pediatric subjects with type 1 diabetes. The run-in period and study period was approximately 120 days long.

The baseline demographics of subjects 7–80 years of age that entered the study period with Fiasp and SmartGuard (i.e. ITT population) are presented below.

Summary of Subject Demographic and Other Baseline (at Screening) Characteristics, ITT Population

Characteristic	Age 7-17 Years (N=107)	Age 18-80 Years (N=116)
Age (Years)		
n	107	116
Mean (SD)	14.0 (2.4)	48.3 (14.5)
Median	15.0	49.0

Characteristic	Age 7-17 Years (N=107)	Age 18-80 Years (N=116)
Min, Max	7.0, 17.0	18.0, 80.0
Gender N (%)		
Female	56 (52.3%)	54 (46.6%)
Male	51 (47.7%)	62 (53.4%)
Country N (%)		
Australia	9 (8.4%)	0 (0.0%)
Canada	9 (8.4%)	7 (6.0%)
United States	89 (83.2%)	109 (94.0%)
Race N (%)		
White	82 (76.6%)	105 (90.5%)
American Indian or Alaska Native,White	1 (0.9%)	0 (0.0%)
Asian,White	2 (1.9%)	0 (0.0%)
American Indian or Alaska Native	0 (0.0%)	1 (0.9%)
Asian	2 (1.9%)	4 (3.4%)
Asian,Native Hawaiian / Other Pacific Islander	1 (0.9%)	0 (0.0%)
Black or African American	7 (6.5%)	5 (4.3%)
Native Hawaiian / Other Pacific Islander	1 (0.9%)	0 (0.0%)
Other (Biracial)	0 (0.0%)	1 (0.9%)
Not reported	11 (10.3%)	0 (0.0%)
Ethnicity N (%)		
Hispanic or Latino	16 (15.0%)	3 (2.6%)
Not Hispanic or Latino	82 (76.6%)	113 (97.4%)
Not reported	9 (8.4%)	0 (0.0%)
Diabetes History (Years)		
n	107	116
Mean (SD)	7.1 (3.3)	29.0 (14.6)
Median	6.9	26.7
Min, Max	1.1, 15.0	2.1, 63.4
Baseline Height (cm)		
n	107	116
Mean (SD)	161.6 (14.3)	171.4 (10.2)
Median	163.8	171.0
Min, Max	122.8, 194.6	150.0, 195.6
Baseline Weight (kg)		
n	107	116
Mean (SD)	61.6 (16.9)	86.2 (19.1)
Median	61.3	87.2
Min, Max	22.1, 105.5	52.4, 139.7
Baseline BMI (Kg/m^2)		
n	107	116
Mean (SD)	23.2 (4.5)	29.3 (6.2)
Median	22.5	28.3
Min, Max	14.7, 36.1	19.0, 54.6
Treatment Method at Baseline		
Closed Loop Therapy (Pump + CGM + Algorithm)	66 (61.7%)	89 (76.7%)
CSII	10 (9.3%)	13 (11.2%)
Other	1 (0.9%)	1 (0.9%)
SAP (Pump + CGM)	30 (28.0%)	13 (11.2%)
Baseline A1C (%)		

Characteristic	Age 7-17 Years (N=107)	Age 18-80 Years (N=116)
n	107	116
Mean (SD)	7.8 (0.9)	7.4 (0.8)
Median	7.7	7.4
Min, Max	5.8, 9.9	5.6, 9.5

For all subjects 7-80 years of age, the Fiasp (insulin aspart), faster-acting insulin injection was used with the MiniMed 780G system and Guardian 4 continuous glucose monitor (CGM) during the Study period with no device-related serious adverse events reported.

The pivotal clinical data with Fiasp (provided in **P160017/S125** and in this submission) confirmed the safety and effectiveness of Fiasp (insulin aspart), faster-acting insulin injection when used in combination with the MiniMed 780G system. The results also confirm that use of Fiasp (insulin aspart) with the MiniMed 780G Auto Correction feature was associated with improved glucose control in all age groups.

Supplemental Clinical Data (AHCL Algorithm)

In Silico Simulation with Guardian 4 Sensor and AHCL (in Type 1) – provided in K251217

In-silico studies and results for AHCL in Type 1 were provided in **K251217**, and the study results provided in this submission are comparable for the compatible configurations of the MiniMed 780G system when used with either the Simplera Sync CGM or the Guardian 4 CGM.

In Silico Simulation with Simplera Sync Sensor and AHCL (in Type 2) – provided in this submission [approved under P160017/S124]

The Type 2 Diabetes (T2D) virtual patient (VP) model matched the T2D adult real patient (RP) population and generated outcomes that are equivalent for time in range (70-180 mg/dL), glucose management indicator (GMI), and a number of other glucose metrics.. In summary, the data shows robust equivalency of characteristics and outcomes between the T2D VPs and T2D RPs in a clinical study setting in CIP341 (**G210352**) Phase 1 for the AHCL algorithm and Guardian 4 sensor (G4S) CGM and CIP341 Phase 2 for the AHCL algorithm) and the DS5 CGM for adults with T2D.

Additionally, the virtual clinical trial in T2D subjects predicted the safety and effectiveness of use of the AHCL algorithm and the G4S CGM, when assessed according to the thresholds

evaluated in CIP341 Phase 2. The thresholds, which reflect the ADA recommendation for percentage time in target range (70-180 mg/dL), were exceeded with statistical significance. These observations support the expectation that real T2D patients could experience a TIR that is at least as favorable as, or significantly greater than, the recommended ADA TIR target when using AHCL with the G4S CGM.

In Silico Simulation with Guardian 4 CGM and AHCL (in Type 1) utilizing Lyumjev and Fiasp insulins – provided in this submission [approved under P160017/S125]

The VP model matched the RP population and generated outcomes that are equivalent for time in range (70-180 mg/dL), GMI, and a number of other glucose metrics. In summary, the data in these analyses shows robust equivalency of characteristics and outcomes between the T1D VPs and RPs in a clinical study setting in CIP335 (**G220010**) and CIP336 (**G210307**) for the AHCL algorithm and the G4S CGM with Lyumjev and Fiasp.

The virtual clinical trial predicted the safety and effectiveness of use of the AHCL algorithm and the G4S and Simplera Sync CGMs when assessed according to the thresholds evaluated in CIP335 and CIP336 for Lyumjev and Fiasp for both type 1 diabetes and type 2 diabetes.

Clinical Testing for Predictive Low Glucose Technology (PLGM Algorithm)

PLGM algorithm was evaluated for safety in a multi-center, single-arm, in-clinic study of the MiniMed 640G System, and study results were provided in **K251217**.

Supplemental Clinical Data (PLGM Algorithm)

In Silico Simulation Studies with PLGM (in Type 2 and Type 1 with Lyumjev/Fiasp) – provided in this submission [reviewed in P160017/S124 and P160017/S125]

PLGM – Type 2 (G210352, CIP341), Lyumjev (G220010, CIP335), Fiasp (G210307, CIP336)

The results for the analyses conducted for the primary endpoint metric of percentage time in hypoglycemia <70 mg/dL fell within the margin for the adult age group, indicating equivalency between the RPs and VPs with regards to time spent below 70 mg/dL with PLGM use.

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 21 CFR 862.1356. The documentation included a description of interface and its specifications, interoperability design and architecture, and the strategy for the Medtronic iAGCs to be interoperable with compatible connected devices (ACE pumps and CGMs). It also specified host device specifications, expectations, interoperability and compatibility requirements, and interface specifications for current and future connected devices. In addition, it provided Medtronic's approach to working with third-party connected device companies regarding contractual issues, quality agreement, data communication and exchange, and post-market reporting procedures and responsibilities.

Predetermined Change Control Plan (PCCP)

A Predetermined Change Control Plan (PCCP) to add potential interoperable connected devices (ACE pumps and iCGMs) in the future, as well as for continued maintenance of previously marketed and qualified connected devices, was provided in accordance with the FDA *Draft* Guidance, *"Predetermined Change Control Plans for Medical Devices (August 2024)"*. It outlined the process for qualifying and integrating additional future connected devices, as well as re-qualification of previously marketed and qualified connected devices to ensure continued compatibility. The PCCP includes a description of modifications, the expected compatibility specifications and the interface specifications for potential future interoperable devices (ACE pumps and iCGMs), a modification protocol (which outlines qualification process and integration test plans with pre-specified acceptance criteria), and an impact assessment.

Conclusion

The subject devices, SmartGuard technology and Predictive Low Glucose technology, have the same intended use and indications for use (except for minor differences in the intended population) and are intended to be used in the same environment as their respective predicate devices, with no differences in technological characteristics between the subject and predicate devices. The required non-clinical and clinical performance data, including in-silico evidence from Virtual Patient Model, provided in this Traditional 510(k) in addition to the data provided in **K251217** demonstrate that the subject devices are as safe and as effective as the predicate devices.

Based on the information provided in this Bundled Traditional 510(k), Medtronic concludes that the subject device, SmartGuard technology, is substantially equivalent to the predicate device, SmartGuard technology for the Product Code QJI, and the subject device, Predictive Low Glucose technology, is substantially equivalent to the predicate device, Predictive Low Glucose technology for the Product Code QJS. Furthermore, the subject devices meet all the iAGC Special Controls requirements defined in 21 CFR 862.1356.