August 29, 2025

Medtronic MiniMed Inc
Hemang Kotecha
Senior Principal Regulatory Affairs Specialist
18000 Devonshire Street
Northridge, California 91325

Re: K251217
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: August 1, 2025
Received: August 1, 2025

Dear Hemang Kotecha:

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
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k251217

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 requiring 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k251217

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 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.

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	Hemang Kotecha Senior Principal Regulatory Affairs Specialist Medtronic MiniMed Inc. Tel: +1 857-203-1151 Email: hemang.kotecha@medtronic.com
Date Prepared	Aug 20, 2025

Device Information

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 Code	QJI, QJS
Device Panel	Clinical Chemistry
Device Class	Class II

Predicate Device Information

Control-IQ Technology (K232382)

Device Description for 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 for ages 7 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.

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 (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 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 device intended for use by people with Type 1 diabetes for ages 7 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 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 (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 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

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, Control IQ Technology for Product Code: QJI

	Subject Device **SmartGuard Technology** **(Advanced Hybrid Closed Loop Algorithm)**	**Predicate Device** **Control IQ Technology** **(K232382)**
Manufacturer	Medtronic MiniMed Inc.	Tandem Diabetes Care, Inc.
Device Trade Name	SmartGuard Technology	Control-IQ 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 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**

	Subject Device **SmartGuard Technology** **(Advanced Hybrid Closed Loop Algorithm)**	**Predicate Device** **Control IQ Technology** **(K232382)**
Prescription Use	Prescription is required	**SAME**
Clinical Application	Type 1 diabetes mellitus	**SAME**
Intended Population	Type 1 diabetes mellitus in persons 7 years of age and greater.	Type 1 diabetes mellitus in persons 2 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**
Compatible CGM	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Medtronic Continuous Glucose Monitors (CGMs)	Integrated Continuous Glucose Monitors (iCGMs)
Communication With ACE Pump	Communicates with an ACE Pump via software interface	**SAME**
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog® Admelog®	U-100 insulin: Novolog® Humalog®
Total Daily Dose (TDD) Of Insulin	8 to 250 units a day	5 to 200 units a day
Active Insulin Time	User adjustable (between 2 - 8 hours)	5 hours
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.	Control-IQ technology can be used to adjust or suspend basal insulin delivery every 5 minutes and automatically deliver correction boluses based on actual and predicted CGM values and target range.

	Subject Device **SmartGuard Technology** **(Advanced Hybrid Closed Loop Algorithm)**	**Predicate Device** **Control IQ Technology** **(K232382)**
Glucose Target (Target Settings)	Glucose Targets (Target Setpoint): • 100 mg/dL • 110 mg/dL • 120 mg/dL Temp Target: 150 mg/dL	Glucose Target (Target Range): • Default: 112.5 - 160 mg/dL • Sleep Mode: 112.5 - 120 mg/dL • Exercise Mode: 140 - 160 mg/dL
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.	When Control-IQ is turned on, the user may choose to enable Sleep or Exercise operating modes. Otherwise, Control-IQ will use the default auto basal operating mode. Control-IQ can transition to a set limited basal delivery rate should conditions arise.
Auto Correction Bolus Target	120 mg/dL	110 mg/dL
Auto Correction Bolus Rate	Calculated at 5-minute intervals	Up to once every 60 minutes
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**
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	There is mandatory user training before the user can use Control-IQ.

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, Control IQ Technology for Product Code: QJS

	Subject Device **Predictive Low Glucose Technology** **(Predictive Low Glucose Management Algorithm)**	**Predicate Device** **Control IQ Technology** **(K232382)**
Manufacturer	Medtronic MiniMed Inc.	Tandem Diabetes Care, Inc.
Device Trade Name	Predictive Low Glucose Technology	Control-IQ 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 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 diabetes mellitus	**SAME**
Intended Population	Type 1 diabetes mellitus in persons 7 years of age and greater.	Type 1 diabetes mellitus in persons 2 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)	Integrated Continuous Glucose Monitors (iCGMs)
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** **Control IQ Technology** **(K232382)**
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog® Admelog®	U-100 insulin: Novolog® Humalog®
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	Manual bolus can be delivered when insulin delivery is suspended
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	There is mandatory user training before the user can use Control-IQ.

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:

- Product Functional Verification (with compatible ACE Pump)
- System Verification Testing (with compatible ACE pump and CGM)

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)

"Safety and Effectiveness Evaluation of the AHCL Algorithm in the MiniMed™ 780G System Used in Combination with the Simplera Sync CGM"

The study evaluated the safety and efficacy of the AHCL algorithm in the MiniMed 780G ACE insulin pump (i.e., study pump) combined with the Simplera Sync CGM for insulin-requiring adults and children with type 1 diabetes in a home setting. This was a multi-center, single-arm study lasting approximately 120 days, involving both adult and pediatric subjects using the compatible MiniMed 780G system, Simplera Sync CGM, and Medtronic Extended infusion set and reservoir. 107 subjects 7-17 years of age and 105 subjects 18-75 years of age completed the study across 25 sites in the U.S.

Protocol Overview

The study included three phases:

1. Screening Period (Visit 1): Participants continued their existing therapy without access to the study device.
2. Run-in Period (Visits 2-6): Participants familiarized themselves with new study devices while using their own insulin brands (Humalog™, NovoLog®, Admelog®). The study pump was used with the Sensor Augmented Pump (SAP) function activated, but SmartGuard™ was turned off, except for those previously using Auto Mode in Medtronic pumps.
3. Study Period (Visits 7-15): Participants used the study pump with SmartGuard enabled, including Auto Correction. The study period was divided into three stages with varying Auto Basal targets and Active Insulin Time settings, adjusted at the investigator's discretion.

Results

Subject baseline characteristics including demographics at enrollment:

Characteristic	Age 7-17 Years Number of Subjects =112	Age 18-80 Years Number of Subjects= 110
AGE (Years)		
Number of Subject N	112	110
Mean (SD)	13.3 (3.0)	46.7 (15.8)
Median	13.0	48.0
Min, Max	7.0, 17.0	18.0, 77.0
Gender N (%)		
Female	48 (42.9%)	56 (50.9%)
Male	64 (57.1%)	54 (49.1%)
Race N (%)		
White	95 (84.8%)	104 (94.5%)
Asian, White	4 (3.6%)	0 (0.0%)
Asian, Native Hawaiian / Other Pacific Islander	0 (0.0%)	1 (0.9%)
American Indian or Alaska Native	0 (0.0%)	1 (0.9%)
American Indian or Alaska Native, Asian, White	1 (0.9%)	0 (0.0%)
American Indian or Alaska Native, White	1 (0.9%)	0 (0.0%)
Asian	2 (1.8%)	1 (0.9%)
Asian, Black or African American	1 (0.9%)	0 (0.0%)
Black or African American	6 (5.4%)	3 (2.7%)
Black or African American, White	1 (0.9%)	0 (0.0%)
Other (Moroccan)	1 (0.9%)	0 (0.0%)
Ethnicity N (%)		
Hispanic or Latino	10 (8.9%)	5 (4.5%)
Not Hispanic or Latino	101 (90.2%)	105 (95.5%)
Not reported	1 (0.9%)	0 (0.0%)
Diabetes History (Years)		
Number of Subject N	112	110
Mean (SD)	7.1 (3.8)	26.0 (14.4)
Median	6.4	24.8
Min, Max	1.2, 16.4	2.6, 60.3
Baseline Height (cm)		
Number of Subjects N	112	110
Mean (SD)	160.1 (15.9)	171.4 (9.1)
Median	162.0	170.1
Min, Max	120.3, 188.9	152.0, 193.6
Baseline Weight (kg)		
Number of Subjects	112	110
Mean (SD)	57.7 (19.3)	84.8 (19.5)
Median	59.1	82.3

Characteristic	Age 7-17 Years Number of Subjects =112	Age 18-80 Years Number of Subjects= 110
Min, Max	25.1, 116.0	46.6, 140.6
Baseline Body Mass Index (kg/m2)		
Number of Subjects	112	110
Mean (SD)	21.9 (4.8)	28.8 (5.9)
Median	21.2	28.2
Min, Max	14.1, 39.7	16.0, 53.2
Treatment Method at Baseline N (%)		
Closed Loop Therapy (Pump + CGM + Algorithm)	96 (85.7%)	82 (74.5%)
CSII	3 (2.7%)	10 (9.1%)
Injection	2 (1.8%)	0 (0.0%)
Other	1 (0.9%)	0 (0.0%)
SAP (Pump + CGM)	10 (8.9%)	18 (16.4%)
Baseline HbA1c (%)		
Number of Subjects N	112	110
Mean (SD)	7.7 (1.0)	7.4 (0.9)
Median	7.8	7.3
Min, Max	5.5, 9.9	5.6, 9.8

Pivotal Safety Results

Subjects Ages 7-17 years

A total of 83 adverse events (AEs) during the study period and one serious adverse event were reported from all investigational sites for 7–17-year-old study subjects enrolled in the study. There were 0 serious adverse events, no reports of severe hypoglycemia, 8 reports of severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs).

Subjects Ages 18-80 Years of Age

A total of 50 adverse events (AEs) during the study period and three serious adverse events were reported from all investigational sites for 18–80-year-old study subjects enrolled in the study.

Pivotal Study Observed Results

The tables below include information on the primary and secondary glycemic results from the run-in period (baseline) to Stage 3 and/or end of 3-month study period. The primary results of the study included change in time in range (70-180 mg/dL) and average HbA1C%.

The overall mean change in HbA1c from baseline to end of 3-month study period is shown in the table below. The percentage of subjects that had an HbA1c value less than 7% at baseline and after the study period changed from 19.6% to 36.9% for subjects aged 7-17, and 30.9% to 68.9% for subjects aged 18 and older.

Difference in HbA1C from Baseline to End of 3-month Study Period

Category	Age 7-17 Years of Age		Age 18-80 Years of Age	
	Baseline	End of Study	Baseline	End of Study
HbA1C (%) Mean ± SD (Median) [N]	7.7 ± 1.0 (7.8) [112]	7.3 ± 0.8 (7.2) [111]	7.4 ± 0.9 (7.3) [110]	6.7 ± 0.5 (6.7) [106]

During the study period, some subjects wore the study pump with the SmartGuard feature and the Auto correction feature turned ON, and with the target setpoint set to either 100 mg/dL, 110 mg/dL, 120 mg/dL, or 150 mg/dL (Temp Target) for at least an entire day.

The table below shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint was used for the entire day during the overall study period. The data in the table below shows that using the SmartGuard feature with the Auto correction feature turned ON and with the 100 mg/dL target setpoint resulted in a lower mean SG value than when the features were used with the 120 mg/dL target setpoint.

Mean Sensor Glucose Values (mg/dL) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Category	Age 7-17 Years					Age 18-80 Years				
	Overall (N = 112)	Target Glucose (mg/dL)				Overall (N = 109)	Target Glucose (mg/dL)			
		100 (N = 109)	110 (N = 12)	120 (N = 111)	150 (N = 52)		100 (N = 107)	110 (N = 5)	120 (N = 108)	150 (N = 48)
Mean Glucose Values During SmartGuard	153.6 ± 14.4	151.9 ± 15.0	149.5 ± 16.5	157.8 ± 14.6	157.3 ± 44.4	143.8 ± 12.2	141.0 ± 11.9	139.8 ± 11.2	150.5 ± 12.4	137.5 ± 29.0

Category	Age 7-17 Years					Age 18-80 Years				
	Overall (N = 112)	Target Glucose (mg/dL)				Overall (N = 109)	Target Glucose (mg/dL)			
		100 (N = 109)	110 (N = 12)	120 (N = 111)	150 (N = 52)		100 (N = 107)	110 (N = 5)	120 (N = 108)	150 (N = 48)
	(150.9, 156.3)	(149.1, 154.8)	(139.0, 160.0)	(155.1, 160.6)	(145.0, 169.7)	(141.4, 146.1)	(138.7, 143.3)	(125.9, 153.7)	(148.1, 152.8)	(129.1, 145.9)

Note 1: Values are presented by Mean ± SD (95% CI).

Note 2: Analysis of data was only performed when SmartGuard Glucose target was used the entire day (e.g., 100 mg/dL set point used for entire day versus 110 mg/dL set point used for entire day versus 120 mg/dL set point used for entire day). Any day with partial usage was excluded from this analysis.

The data in the table below show that using the SmartGuard feature with the Auto correction feature turned ON maintained the sensor glucose (SG) values in range and reduced time above range. Specifically, adult subjects spent more time in range (70–180 mg/dL) and less time in hypoglycemia (<70 mg/dL) and hyperglycemia (>180 mg/dL) during stage 3 of the study period compared with the run-in period. Pediatric subjects spent more time in range (70–180 mg/dL) and less time in hyperglycemia (>180 mg/dL) without significantly increasing time in hypoglycemia (<70 mg/dL) during stage 3 of the study period compared with the run-in period.

Percentage of SG values in Different Ranges during the Run-In Period and Study Period Stage 3

Category	SG Range (mg/dL)	Age 7-17 Years		Age 18-80 Years	
		Run-in period (N = 112)	Study Period Stage 3 (N = 109)	Run-in period (N = 110)	Study Period Stage 3 (N = 107)
Low SG Value	<54	0.3 ± 0.6 (0.2, 0.4)	0.4 ± 0.3 (0.3, 0.4)	0.3 ± 0.5 (0.2, 0.4)	0.2 ± 0.4 (0.1, 0.3)
	<70	1.6 ± 1.7 (1.3, 1.9)	1.9 ± 1.4 (1.7, 2.2)	1.7 ± 1.9 (1.4, 2.1)	1.5 ± 1.4 (1.3, 1.8)
Target SG Value	70 – 140	32.1 ± 14.1 (29.5, 34.7)	49.2 ± 9.7 (47.4, 51.0)	39.2 ± 13.0 (36.8, 41.7)	56.1 ± 10.5 (54.1, 58.1)
	70 – 180	54.4 ± 15.7 (51.5, 57.3)	71.4 ± 9.9 (69.5, 73.3)	66.5 ± 12.6 (64.1, 68.8)	80.2 ± 8.1 (78.7, 81.8)
High SG Value	> 140	66.3 ± 14.7 (63.5, 69.0)	48.9 ± 10.0 (47.0, 50.8)	59.1 ± 13.9 (56.4, 61.7)	42.4 ± 11.0 (40.3, 44.5)
	> 180	44.0 ± 16.1 (41.0, 47.0)	26.7 ± 10.1 (24.7, 28.6)	31.8 ± 13.1 (29.4, 34.3)	18.2 ± 8.4 (16.6, 19.9)
	> 250	16.4 ± 11.1 (14.3, 18.5)	8.0 ± 6.6 (6.8, 9.3)	7.4 ± 6.1 (6.2, 8.5)	3.4 ± 3.0 (2.8, 4.0)

Category	SG Range (mg/dL)	Age 7-17 Years		Age 18-80 Years	
		Run-in period (N = 112)	Study Period Stage 3 (N = 109)	Run-in period (N = 110)	Study Period Stage 3 (N = 107)
	> 350	2.4 ± 3.5 (1.8, 3.1)	1.3 ± 2.2 (0.9, 1.8)	0.4 ± 0.7 (0.3, 0.5)	0.3 ± 0.5 (0.2, 0.4)

Supplemental Clinical Data

In Silico Simulation Studies Description to Support use of Guardian 4 Sensor and AHCL

Simulation studies were conducted with various setpoint combinations (100, 110 and 120 mg/dL) and active insulin time (AIT) set to 2, 3 or 4 hours to enable the studying of in-silico outcomes with various parameter settings. The virtual patients were simulated using the MiniMed™ 780G ACE insulin pump with updated AHCL algorithm with Guardian 4 sensor models for an in-silico protocol of 88 days.

Medtronic evaluated the *in-silico* glucose therapy outcomes for an insulin dependent type 1 diabetes virtual patient population using Medtronic Diabetes' simulation environment.

For the simulation studies, across the virtual patients, the highest average time in range (TIR) (81.8% ± 8.3%) is achieved with the settings of controller-target of 100 mg/dL and AIT of 2 hours. These settings also result in the highest average Time Below Range (TBR) (2.3% ± 1.9%). The lowest average TBR (1% ± 1.1%) is achieved with the settings of controller-target of 120 mg/dL and AIT of 4 hours across all virtual patients. These settings also result in the lowest average TIR (76% ± 9.9%) across all virtual patients.

For all age-groups, the average TBR (% time < 70 mg/dL) is within ADA guidelines of 4% with all studied in-silico settings of setpoint and AIT. The average % time below 54 mg/dL is within ADA guidelines of < 1% for all age groups with the 100, 110, and 120 mg/dL set point at the studied AIT of 4 hours, and with the 110 and 120 mg/dL set point at the studied AIT of 3 hours.

Based on the in-silico studies and results, the study results are comparable for the compatible MiniMed 780G system when used with either the Simplera Sync CGM or the Guardian 4 CGM. Although the Simplera Sync sensor was used in the clinical study, in-silico testing indicates that the performance of the system with the Guardian 4 sensor and Guardian 4 transmitter, compared to the Simplera Sync sensor, is expected to be clinically equivalent.

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. This feature is the same in the compatible Medtronic AID System (MiniMed 780G system). Study subjects included persons aged 14 to 75 years diagnosed with type 1 diabetes mellitus who were on pump therapy at the time of screening.

A total of 71 subjects were subjected to hypoglycemic induction, followed by an observation period. For hypoglycemic induction, the target was set to 65 mg/dL, using the rate of change basal increase algorithm. PLGM was activated with the Low Limit setting for the Suspend before low feature ON set to 65 mg/dL, and the subject was observed with frequent sample testing (FST, or frequent blood sampling for glucose measurements) for a maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after basal insulin delivery resumed.

Performance and Safety

Of the 71 subjects with induced hypoglycemia, 69 inductions were successful, 27 subjects experienced a hypoglycemic event and 42 subjects did not. At 120 minutes after the start of the pump suspension events, the mean reference glucose value (measured using a Yellow Springs Instrument [YSI™]) was 102 ± 34.6 mg/dL.

Five (5) adverse events were reported during the study. Four adverse events were neither device nor procedure related. One adverse event was procedure related.

Data from this in-clinic study demonstrated that PLGM algorithm is safe to use. Study success criteria, as defined in the protocol, were met (i.e., there were no device related serious adverse events, no diabetic ketoacidosis events related to PLGM algorithm, and no unanticipated adverse device effects).

Clinical study overview (Ages 7-13 Years)

PLGM algorithm was also evaluated in a study of the MiniMed 670G system that included subjects 7-13 years, diagnosed with type 1 diabetes mellitus. This feature is the same in the compatible Medtronic AID System (MiniMed 780G system).

A total of 105 study subjects were observed overnight after exercise/activity while using the system with the Suspend before low feature activated. The Low Limit setting for PLGM turned ON was set to 65 mg/dL and the subjects were observed with FST for a maximum of 12 hours.

Feature performance and safety

In 79.7% of cases, after activation of PLGM, the threshold of ≤ 65 mg/dL was avoided. Mean glucose levels up to six hours after the suspend feature was activated remained below the starting glucose levels. Data from this in-clinic evaluation demonstrated that PLGM is safe to use in a pediatric population.

Virtual Patient Model

Medtronic conducted extensive validation of the simulation environment and established the credibility of the virtual patient (VP) model according to the Context of Use (COU), following the framework from, *"Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions: Guidance for Industry and FDA Staff"*, issued on November 17, 2023. In-silico evidence from the VP model demonstrated safety and effectiveness of the AHCL and PLGM algorithms with compatible iCGMs, compatible interoperable Medtronic CGMs and compatible ACE pumps. Additionally, an equivalency was demonstrated between Real Patients (RPs) and Virtual Patients (VPs) in terms of predetermined characteristics and clinical outcomes and data showed equivalent glycemic outcomes between the T1D Virtual Patients and Real Patients in a clinical study setting for the AHCL and PLGM algorithms with compatible interoperable Medtronic CGMs and compatible iCGMs.

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 similar indications for use and are intended to be used in the same environment as their respective predicate devices. While there are minor differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety and effectiveness. The required non-clinical and clinical performance data, including in-silico evidence from Virtual Patient Model, provided in this Traditional 510(k) demonstrate that the subject devices are as safe and as effective as the predicate devices.

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