February 3, 2026

Medtronic Minimed
Shivani Shah
Senior Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 91325

Re: K253701
Trade/Device Name: SmartGuard Technology
Predictive Low Glucose Technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI, QJS, NDC
Dated: November 21, 2025
Received: November 24, 2025

Dear Shivani Shah:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253701

Please provide the device trade name(s).

SmartGuard Technology
Predictive Low Glucose Technology

Please provide your Indications for Use below.

SmartGuard Technology:

SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.
SmartGuard technology is intended for the management of Type 1 diabetes mellitus in persons 7 years of age and older, and Type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.
SmartGuard technology is intended for single patient use and requires a prescription.

Predictive Low Glucose Technology:

Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values.
Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data.
Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.
Predictive Low Glucose technology is intended for single patient use and requires a prescription.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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

510(k) Submitter and Device Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Shivani Shah Senior Regulatory Affairs Specialist Medtronic MiniMed Inc. shivani.a.shah@medtronic.com
Alternate Contact Person	Siddhi Rasam Senior Regulatory Affairs Manager Medtronic MiniMed Inc. siddhi.rasam@medtronic.com
Device Trade Name	SmartGuard Technology, Predictive Low Glucose Technology
Device Common Name	Advanced Hybrid Closed Loop Algorithm, Predictive Low Glucose Management Algorithm
Device Classification Name	Interoperable Automated Glycemic Controller
Regulation Number	21 CFR 862.1356
Product Codes	QJI, QJS, NDC
Predicate Device	K251217 - SmartGuard Technology and Predictive Low Glucose Technology K251032 - MiniMed 780G insulin pump
Device Panel	Clinical Chemistry
Device Class	Class II

Device Description for SmartGuard Technology

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

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

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

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

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

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

Indications for Use / Intended Use for SmartGuard Technology

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

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

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

Device Description for Predictive Low Glucose Technology

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

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

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

Indications for Use / Intended Use for Predictive Low Glucose Technology

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

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

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

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

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

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

	Predicate Device SmartGuard Technology (Advanced Hybrid Closed Loop (AHCL) Algorithm) (K251217)	**Subject Device SmartGuard Technology (Advanced Hybrid Closed Loop (AHCL) Algorithm)**
Manufacturer	Medtronic MiniMed Inc.	**SAME**
Device Trade Name	SmartGuard Technology	**SAME**
Device Classification	Class II	**SAME**
Product Code	QJI	**SAME**
Regulation Name	Interoperable Automated Glycemic Controller (under 21 CFR 862.1356)	**SAME**
Indications For Use/Intended Use	SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM) 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.	SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values. SmartGuard technology is intended for the management of Type 1 diabetes mellitus in persons 7 years of age and older, and Type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. SmartGuard technology is intended for single patient use and requires a prescription.
Prescription Use	Prescription is required	**SAME**

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

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

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

[1] SmartGuard Technology for the management of Type 2 diabetes is cleared under K253585.
[2] The use of Lyumjev and Fiasp insulins is cleared under K253470.

Regulation Name	Interoperable automated glycemic controller, insulin suspend (under 21 CFR 862.1356)	**SAME**
Indications For Use/Intended Use	Predictive Low Glucose Technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM) 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.	Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values. Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data. Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. Predictive Low Glucose technology is intended for single patient use and requires a prescription.
Prescription Use	Prescription is required	**SAME**
Environment Of Use	Professional healthcare facilities and home environments	**SAME**
Intended Population	Type 1 diabetes mellitus in persons 7 years of age and greater.	Type 1 diabetes mellitus in persons 7 years of age and greater. Type 2 diabetes mellitus in persons 18 years of age and greater.[3]
Number Of Users	Single user	**SAME**
Principle Of Operation	Algorithmic software device that utilizes CGM sensor readings to stop and resume insulin based on the current and predicted (30 minutes into the future) sensor values.	**SAME**
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog® Admelog®	U-100 insulin:[4] Novolog® Humalog® Admelog® Fiasp® Lyumjev®
Can Automatically Resume Insulin Delivery	Yes	**SAME**
Basal Insulin Delivery Suspension	Suspend on Low: Based on the current CGM value is less than or equal to the low limit (50 to 90 mg/dL).	**SAME**

[3] Predictive Low Glucose technology for the management of Type 2 diabetes is cleared under K253585.
[4] The use of Lyumjev and Fiasp insulins is cleared under K253470.

	Suspend before Low: Based on 30 minute predictive CGM value is less than equal to low limit (50 to 90 mg/dL) and current sensor glucose values.	
Bolus Insulin Delivery Suspension	Any ongoing bolus delivery will be cancelled.	**SAME**
	Minimum – 30 minutes Maximum - 2 hours User can resume delivery at any time	**SAME**
Predetermined changed control plan (PCCP)	The MiniMed 780G insulin pump was cleared with an authorized PCCP that included modifications for integrating with additional interoperable devices in the future.	**SAME**

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

	Subject Device **MiniMed 780G ACE pump (K251032)**	**Subject Device** **Predictive Low Glucose Technology (Predictive Low Glucose Management (PLGM) Algorithm)**
Manufacturer	Medtronic	**SAME**
Device Trade Name	MiniMed 780G ACE insulin pump	Predictive Low Glucose Technology
Device Type	Predictive Pulmonary-Function Value Calculator (21 CFR 868.1890)	**SAME**
Device Classification	Class II	**SAME**
Product Code	NDC	**SAME**
Indications for Use/Intended Use	The 780G Pump contains a bolus calculator that calculates an insulin dose based on user-entered data.	Predictive Low Glucose technology contains a bolus calculator that calculates an insulin dose based on user-entered data.
Therapy Type	Diabetes patients treated with insulin pump therapy in which calculator is integrated	**SAME**
Specific Drug/Biological Use	U-100 insulins	**SAME**
Principles of Operation	Calculate insulin doses for meals and corrections while accounting for active insulin (insulin on board).	**SAME**
Carbohydrate Calculator	Calculates carbohydrate intake based on user-entered data.	**SAME**
Manual Data Entry	Yes	**SAME**

Requires BG for calculation	Yes	**SAME**

Summary of Non-Clinical Performance Data

Medtronic MiniMed conducted performance testing for SmartGuard Technology and Predictive Low Glucose Technology, summarized below, to demonstrate substantial equivalence to the predicate devices and to ensure that the subject devices meet all applicable iAGC Special Controls requirements defined in 21 CFR 862.1356.

Special Controls

Evaluation and adherence to the Special Controls of the Predicate Device (K251217) demonstrates continued assurance of the safety and effectiveness of the Subject Devices.

Software Verification and Validation

Software verification activities were performed in accordance with ISO 14971:2019, "Medical Devices - Application of Risk Management to Medical Devices," IEC 62304:2006/A1:2016, "Medical Device Software - Software Life Cycle Processes," and FDA guidance, "*Content of Premarket Submissions for Device Software Functions*" (June 2023).

Additionally, cybersecurity activities were all completed per a 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.

Interoperability

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

Human Factors Validation

A human factors and usability engineering process was performed on Subject Devices with compatible Medtronic CGM and compatible Medtronic ACE pump 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

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

Pre-determined Change Control Plan (PCCP)

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

Summary of Clinical Performance Data

The SmartGuard Technology and Predictive Low Glucose Technology remains consistent with previously cleared algorithm designs and indications with no changes to the algorithm design, architecture, features, logical flows, safeguards, or principles of operation from the AHCL and PLGM algorithms previously reviewed and cleared by the FDA under **K251217** as iAGCs. The indication for the SmartGuard Technology and Predictive Low Glucose Technology expanded from Type 1 diabetes management to Type 2 diabetes management (cleared under **K253585**) and compatibility with additional U-100 insulins, Fiasp and Lyumjev (cleared under **K253470**).

All clinical evidence referenced in this 510(k) is identical to evidence previously reviewed and subsequently cleared by the FDA.

Virtual Patient Model

The Virtual Patient (VP) model was used to demonstrate safety and effectiveness of the iAGC algorithms with compatible iCGMs, compatible interoperable Medtronic CGM, and compatible ACE pumps. The validation activities of the virtual patient model—following the framework from FDA Guidance, "*Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions: Guidance for Industry and FDA Staff*" (November 2023)—remain unchanged from what was provided in K25127, P160017/S124, and P160017/S125.

Medtronic demonstrated equivalency between the VPs and real patients (RPs) in terms of fixed acceptance criteria from pivotal clinical studies for the AHCL and PLGM algorithms:

- CIP335 (Lyumjev); **G220010**
- CIP336 (Fiasp); **G210307**; and
- CIP341(Type 2); **G210352**

The equivalency testing provided for CIP337 (G220306) remains unchanged from what was provided in K251217.

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, with minor technological differences that do not raise new safety or effectiveness questions. Non-clinical and clinical performance data, including Virtual Patient Model in silico evidence, demonstrate both subject devices meet all iAGC Special Controls requirements per 21 CFR 862.1356 and provide a reasonable assurance of safety and effectiveness and establish SmartGuard Technology as substantially equivalent to predicate SmartGuard Technology (Product Code QJI) and Predictive Low Glucose Technology as substantially equivalent to predicate Predictive Low Glucose Technology (Product Code QJS) and MiniMed 780G insulin pump (Product Code NDC).