510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K251217

B Applicant

Medtronic MiniMed Inc.

C Proprietary and Established Names

SmartGuard technology

Predictive Low Glucose technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	Class II	21 CFR 862.1356 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry
QJS	Class II	21 CFR 862.1356 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry

E Purpose for Submission:

- Clearance of the SmartGuard technology and the Predictive Low Glucose technology as interoperable automated glycemic controllers (iAGCs).
- Establish a Predetermined Change Control Plan (PCCP) for qualifying and integrating with compatible FDA-cleared integrated continuous glucose monitors (iCGMs) and compatible FDA-cleared alternate controller enabled (ACE) pumps.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Indication(s) for 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 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 requiring insulin.

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

C Special Conditions for Use Statement(s):

SmartGuard Technology
Rx - For Prescription Use Only

- SmartGuard technology is contraindicated for use in persons under age 7.
- SmartGuard technology is not recommended for people with a significant cognitive or physical impairment that affects their ability to safely operate the pump, including a lack of physical dexterity.
- SmartGuard technology is not recommended for children who are not under the care of a parent or caregiver who is capable of safely operating the pump for the patient.
- SmartGuard technology is not recommended for persons who are unwilling or unable to perform BG meter readings.
- SmartGuard technology is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.
- Do not use the SmartGuard feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to use the SmartGuard feature.

Predictive Low Glucose Technology
Rx - For Prescription Use Only

- Predictive Low Glucose technology is contraindicated for use in persons under age 7.

- Predictive Low Glucose technology is not recommended for people with a significant cognitive or physical impairment that affects their ability to safely operate the pump, including a lack of physical dexterity.
- Predictive Low Glucose technology is not recommended for children who are not under the care of a parent or caregiver who is capable of safely operating the pump for the patient.
- Predictive Low Glucose technology is not recommended for persons who are unwilling or unable to perform BG meter readings.
- Predictive Low Glucose technology is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

III Device Description

SmartGuard Technology

The SmartGuard Technology, also referred to as the 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 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.

Inputs to the AHCL algorithm (e.g., SG values, user inputs) are received from the ACE pump, and outputs from the AHCL algorithm (e.g., insulin delivery commands) are sent by the algorithm to the ACE pump.

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. 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 5 consecutive hours of insulin delivery history, a minimum of 2 days of total daily dose (TDD) of insulin, a valid SG and blood glucose (BG) values to start automated insulin delivery.

Predictive Low Glucose Technology

The 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 iAGC that is intended for use with compatible iCGMs, compatible Medtronic CGMs and compatible ACE pumps to automatically suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

Inputs to the PLGM algorithm (e.g., SG 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 via software interface.

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.

IV Substantial Equivalence Information:

A Predicate Device Name(s):
Control-IQ Technology

B Predicate 510(k) Number(s):
K232382

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251217	K232382
Device Trade Name	SmartGuard technology	Control-IQ technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	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.	Same
Principles of Operation	Algorithmic software device intended to automatically increase, decrease, suspend and resume delivery of insulin based on sensor glucose values	Same
Device Hosting Controller	ACE Pump	Same
Communication with ACE Pump	Software interface	Same
General Device Characteristic Differences		

Intended Use Population	7 years and older with type 1 diabetes mellitus	2 years and older with type 1 diabetes mellitus
Insulin Type	U-100 insulin: Novolog, Humalog, Admelog	U-100 insulin: Novolog, Humalog
Compatible CGM	Integrated Continuous Glucose Monitors (iCGMs), qualified Medtronic Continuous Glucose Monitors (Simplera Sync, Guardian 4 Sensor)	iCGMs
Total Daily Dose (TDD) of Insulin	8 to 250 units a day	5 to 200 units a day
Active Insulin Time	Between 2-8 hours (user adjustable)	5 hours
Auto Correction Bolus Rate	Calculated at 5-minute intervals	Up to once every 60 minutes
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

Device & Predicate Device(s):	K251217	K232382
Device Trade Name	Predictive Low Glucose technology	Control-IQ technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	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	Same

	predefined threshold values.	
Device Hosting Controller	ACE Pump	Same
Principles of Operation	Algorithmic software device that utilizes CGM sensor readings to suspend and resume insulin based on the current and predicted sensor values	Same
General Device Characteristic Differences		
Intended Use Population	7 years and older with type 1 diabetes mellitus	
Insulin Type	U-100 insulin: Novolog, Humalog, Admelog	
Compatible CGM	Integrated Continuous Glucose Monitors (iCGMs), qualified Medtronic Continuous Glucose Monitors (Simplera Sync, Guardian 4 Sensor)	iCGMs

V Standards/Guidance Documents Referenced:

- Special controls established under 21 CFR 862.1356
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION 13-79 Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION 15-129 Medical devices - Part 1: Application of usability engineering to medical devices

VI Performance Characteristics (if/when applicable):

A. Analytical Performance

Not applicable.

B. Other Supportive Instrument Performance Characteristics Data

Clinical Performance Data

No new clinical studies were conducted to support substantial equivalence of the subject devices. The subject SmartGuard technology algorithm was previously approved as part of the MiniMed 780G System under P160017/S118. The subject Predictive Low Glucose technology algorithm was previously approved as part of the MiniMed 670G System under P160017, including P160017/S031, as well as the MiniMed 780G System under P160017/S118. SmartGuard technology and Predictive Low Glucose technology are the same algorithms as reviewed in these respective PMAs, with the exception of the updated intended uses to include interoperability and the PCCP described below. Therefore, prior pivotal clinical data were leveraged from P160017, P160017/S031, and P160017/S118. Summaries of the results of these prior clinical studies are provided in the Summary of Safety and Effectiveness Data (SSED) for those submissions.

Non-Clinical Performance Data

There have been no changes to the SmartGuard technology's design, architecture, features, logical flows, or principles of operation from the version approved under P160017/S118 (version 5.3A), nor changes to the Predictive Low Glucose technology's design, architecture, features, logical flows, or principles of operation since the version approved under P160017 (version 1.0.0.0). Therefore, non-clinical studies were leveraged from previous submissions. For example, prior non-clinical information included: Software Verification and Validation, Data Logging, Cybersecurity, and Human Factors Validation.

The sponsor conducted additional product functional verification activities with the 780G ACE pump SW 6.42 (cleared under K251032) and system verification activities with the 780G ACE pump SW 6.42 with qualified compatible Medtronic CGMs (Simplera Sync and Guardian 4 Sensor approved under P250012) to confirm that the controllers perform as intended and meet all specified requirements, including iAGC design verification and validation special controls.

Interoperability

A plan and approach for interoperability were provided and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications for potential interoperable devices. Provided interoperability documentation included a description of the respective device interface and its specifications, interoperability design and architecture, and the strategy for the subject iAGCs to be interoperable with compatible connected devices, including the PCCP described below. The SmartGuard technology and Predictive Low Glucose technology algorithms are designed to be interoperable with the qualified Medtronic Simplera Sync and Guardian 4 Sensor, qualified Medtronic ACE pumps, and qualified iCGMs. In addition, their plan provided Medtronic's approach to working with third-party connected iCGM device companies regarding contractual issues, quality agreement, data communication and exchange, and post-market reporting procedures and responsibilities.

Hazard Analysis

Hazard analyses were provided for the SmartGuard technology and Predictive Low Glucose technology algorithms, respectively, in which risks and risk mitigations for software and interoperable hardware components associated with the safe and effective functioning of the

devices were provided, as well as verification and validation activities for implemented risk control measures. In particular, these hazard analyses accounted for the risks associated with interoperability between the software devices developed by the sponsor and other third-party interoperable devices (i.e, iCGMs).

PCCP

This submission included a PCCP that Medtronic will follow (1) for qualifying and integrating new compatible iCGMs and ACE pumps and (2) for continued maintenance of previously marketed and qualified connected iCGMs and ACE pumps. The PCCP includes a description of the modifications, a modification protocol, and an impact assessment. The PCCP specifies the testing methods, validation activities, and performance requirements to implement the specified modifications such that SmartGuard technology and Predictive Low Glucose technology remain as safe and as effective as their predicate device and continue to comply with 21 CFR 862.1356(b). The sponsor's PCCP comprises the following for each subject iAGC:

- A new candidate iCGM must have demonstrated compatibility to established minimum iCGM performance, compatibility, and sensor specifications FDA found appropriate during this review before proceeding with qualification.
- Medtronic will conduct virtual clinical trial testing with virtual patients, with pre-defined acceptance criteria based on virtual patient equivalency testing and glycemic outcomes from the iAGC clinical study. Software design integration of the new iCGM with the subject iAGC will then be completed, and integration V&V testing will be conducted according to the established PCCP. If integration V&V testing meets the PCCP's prespecified acceptance criteria, the iCGM may be added as an interoperable component to the subject iAGC
- A new candidate ACE pump must have demonstrated compatibility to established minimum ACE pump compatibility and performance specifications defined in the PCCP before proceeding to software design integration with the subject iAGC. Integration V&V testing will then be conducted according to the established PCCP. If integration V&V testing meets the PCCP's prespecified acceptance criteria, the ACE pump may be added as an interoperable component to the subject iAGC.
- Modifications to previously marketed and qualified iCGM and ACE pump devices will be evaluated and, as needed, re-qualified according to the PCCP. For iCGMs, re-qualification requires demonstrated continued compatibility to the minimum iCGM specifications, virtual clinical trial testing as needed, and integration V&V testing. Modified ACE pumps are re-qualified through demonstrated continued compatibility to the minimum ACE pump specifications defined in the PCCP and successful integration V&V testing.
- Related iAGC labeling will be revised as needed to identify new qualified and integrated compatible devices or to remove previously compatible devices found to no longer be compatible. Communication will be provided through various channels to notify users about a new compatible device or previously compatible but now incompatible device.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device and met the special controls for 21 CFR 862.1356.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.