



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K253585

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:

Modifications to a cleared device, including:

- Expansion of the intended use population to include people with Type 2 diabetes
- Expansion of compatible U-100 insulins to include Lyumjev® and Fiasp®
- Modification of 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 to cover the addition of a new patient population (Type 2 diabetes), additional compatible U-100 insulins, along with a new ACE Pump and new iCGM.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

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, and by people with Type 2 diabetes, ages 18 years or older requiring insulin.

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

Predictive Low Glucose Technology

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

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

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

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.

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

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, and by people with Type 2 diabetes, ages 18 years or older. It is an interoperable automated glycemic controller (iAGC) that is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible interoperable Medtronic continuous glucose monitors (CGM) and compatible alternate controller enabled (ACE) pumps to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.

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

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

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, and by people with Type 2 diabetes, ages 18 years or older. It is an interoperable automated glycemic controller (iAGC) that is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible interoperable Medtronic

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

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

Inputs to PLGM algorithm (e.g., sensor glucose values, user inputs) are received from the ACE pump (host device), and outputs from PLGM algorithm (e.g., suspend/resume commands) are sent by the algorithm to the ACE pump *via software interface*. 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.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

SmartGuard technology

Predictive Low Glucose technology

B Predicate 510(k) Number(s):

K251217

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253585	K251217
Device Trade Name	SmartGuard Technology	SAME
General Device Characteristic Similarities		
Intended Use/Indications for Use	SmartGuard technology is intended for use with compatible continuous glucose monitors (CGM)	SAME

	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.	
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	Communicates with an ACE Pump via software interface	SAME
Number of Users	Single User	SAME
Alarms/Alerts	ACE pump will display algorithm-related alerts to the user	SAME
Auto Mode Exit	Algorithm automatically de-activates and exits auto mode when conditions arise	SAME
Manual Algorithm Deactivation	User can manually turn off closed loop therapy	SAME
Meal/Food Bolus	Users must manually deliver meal boluses they can calculate using the integrated bolus calculator. An SG or BG value is used for meal boluses.	SAME
Mechanism of Software Update	Firmware over the Air	SAME
Training	There is mandatory user	SAME

	training before the user can use AHCL Algorithm	
General Device Characteristic Differences		
Intended Use Population	Type 1 diabetes mellitus in persons 7 years of age and greater. Type 2 diabetes mellitus in persons 18 years of age and greater.	Type 1 diabetes mellitus in persons 7 years of age and greater.
Specific Drug/Biological Use	U-100 insulin: Novolog [®] Lyumjev [®] Humalog [®] Fiasp [®] Admelog [®]	U-100 insulin: Novolog [®] Humalog [®] Admelog [®]

Device & Predicate Device(s):	K253585	K251217
Device Trade Name	Predictive Low Glucose Technology	SAME
General Device Characteristic Similarities		
Intended Use/Indications for 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
Principles of Operation	Algorithmic software device that utilizes CGM sensor readings to	SAME

	suspend and resume insulin based on the current and predicted sensor values.	
Device Hosting Controller	ACE Pump	SAME
Communication with ACE Pump	Communicates with an ACE Pump via software interface	SAME
Number of Users	Single User	SAME
Alarms/Alerts	ACE pump will display algorithm-related alerts to the user	SAME
Manual Algorithm Deactivation	User can manually turn off the therapy/algorithm	SAME
Mechanism of Software Update	Firmware over the Air	SAME
Training	There is mandatory user training before the user can use PLGM Algorithm	SAME
General Device Characteristic Differences		
Intended Use Population	Type 1 diabetes mellitus in persons 7 years of age and greater. Type 2 diabetes mellitus in persons 18 years of age and greater.	Type 1 diabetes mellitus in persons 7 years of age and greater.
Specific Drug/Biological Use	U-100 insulin: Novolog [®] Lyumjev [®] Humalog [®] Fiasp [®] Admelog [®]	U-100 insulin: Novolog [®] Humalog [®] Admelog [®]

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

The subject SmartGuard Technology algorithm was previously approved for use, including by people with type 2 diabetes and for use with Fiasp and Lyumjev, as part of the MiniMed 780G System under P160017/S118, P160017/S124, and P160017/S125. 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, P160017/S118, P160017/S124, and P160017/S125. Refer to the Summary of Safety and Effectiveness Data (SSED) for those submissions for a summary of those clinical studies. No new clinical studies were conducted to support substantial equivalence of the subject devices.

Non-Clinical Performance Data

There have been no changes to the SmartGuard technology's design, architecture, features, logical flows, safeguards or principles of operation from the AHCL algorithm approved under P160017/S118, P160017/S124, and P160017/S125 (version 5.3A) or PLGM algorithm approved under in P160017 (version 1.0.0.0). Both algorithms were subsequently cleared in K251217 as Medtronic iAGCs. Therefore, non-clinical studies were leveraged from previous submissions.

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 Simplerla 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 an updated version of the PCCP originally cleared in K251217 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 trials with virtual patients, with pre-defined acceptance criteria based on virtual patient equivalency testing and glycemic outcomes from the iAGC clinical studies. 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. As part of this 510(k), the scope of these virtual clinical studies (previously described in the PCCP for K251217) was expanded to address device use in type 2 diabetes, as well as the use of Fiasp and Lyumjev insulin products. Specific test cases and pre-specified acceptance criteria were added to address these new uses.
- 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.