510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253701

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	II	21 CFR 862.1356	Clinical Chemistry
NDC	II	21 CFR 868.1890	Clinical Chemistry

E Purpose for Submission:

Modifications to a cleared device. The subject devices are modified as follows:

- New user interface, "MiniMed App," installed on a smartphone
- A predetermined change control plan focused on making device changes to enable and maintain device interoperability with continuous glucose monitors and insulin pumps.

The devices reviewed in this submission include other changes compared to the predicate device which were cleared in separate submissions as described below:

- K253585: IFU expansion to include people with Type 2 Diabetes 18 years of age and older requiring insulin
- K253585: Addition of U-100 insulins Lyumjev® and Fiasp® as compatible insulins

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use statement

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 (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.

C Special Conditions for Use Statement(s):

SmartGuard Technology:
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:
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

MiniMed SmartGuard Technology and Predictive Low Glucose Technology algorithms are interoperable automated glycemic controllers (iAGC) that are core software components of MiniMed's automated insulin delivery (AID) systems.

The SmartGuard and Predictive Low Glucose Technology algorithms are embedded in the firmware of a compatible ACE pump and allow the pump to operate in two different modes based on which of the subject MiniMed iAGCs is active:

- SmartGuard Mode (also referred to as "Auto Mode") or
- Manual Mode with the Predictive Low Glucose Technology algorithm.

The MiniMed App provides the primary display and user interface for the MiniMed iAGCs when connected to a compatible screenless ACE pump. The MiniMed App is a software application installed on a compatible mobile device with the iOS or Android operating system. The MiniMed App is a component of the iAGCs and serves as the primary display and user interface (UI) for the MiniMed iAGCs and compatible screenless ACE pump.

The MiniMed App digitally communicates with the following devices:

- Compatible ACE pumps through Bluetooth Low Energy (BLE),
- Compatible iCGMs/Medtronic MiniMed CGMs via the ACE pump,
- Cloud-based services through an available cellular or Wi-Fi connection for backend processing and connection to the CareLink Therapy Management System.

The MiniMed App allows for user interaction with the connected devices of the AID system. Key features of the app include:

- Pairing and viewing the status of connected devices;
- Facilitating reservoir or infusion set changes;
- Displaying current and historical insulin therapy, sensor glucose activity, and status (e.g. sensor glucose (SG) values and trends, status, alarms, advisories and messages);

- Setting up and making changes to settings (e.g. insulin delivery, sensor glucose and alarm/alert settings); and
- Sending user-initiated requests or inputs to the connected devices (e.g. bolus calculation requests, manual bolus requests, and logging blood glucose).

The MiniMed App remains active, receiving and sending data, while running in either the foreground or background (i.e., when the user is using their mobile device for other tasks). Users must log in with a CareLink account before they can use the MiniMed App and pair/interact with connected devices.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

SmartGuard Technology

B Predicate 510(k) Number(s):

K251217

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251217	K253701
Device Trade Name	**SmartGuard Technology**	**SmartGuard Technology**
General Device Characteristic Similarities		
Intended Use/Indications For 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	**Same**

	intended for single patient use and requires a prescription.	
Product Code	QJI	**Same**
Prescription Use	Prescription is required	**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**
Glucose Target (Target Settings)	100 mg/dL 110 mg/dL 120 mg/dL Temp Target: 150 mg/dL	**Same**
Auto Correction Bolus Target	120 mg/dL	**Same**
Meal / Food Bolus	Manual input of meal size for delivery of bolus either through blood glucose based insulin dose calculator or through iAGC	**Same**
Compatible Continuous Glucose Monitoring Systems	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Medtronic MiniMed Continuous Glucose Monitors (CGMs)	**Same**
General Device Characteristic Differences		
Intended Populations	Type 1 diabetes mellitus in persons 7 years of age and greater.	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
Compatible U-100 Insulins	Novolog® Humalog® Admelog®	Novolog® Humalog® Admelog® Lyumjev® Fiasp®
Alerts/Alarms	Compatible ACE pump displays algorithm-related alerts/alarms	MiniMed app will display alerts/alarms on user's smartphone or dedicated handheld device, or Compatible ACE pump displays algorithm-related alerts/alarms
Primary User Interface	ACE Pump	MiniMed app and compatible ACE Pump

Device & Predicate Device(s):	K251217	K253701
Device Trade Name	**Predictive Low Glucose Technology**	**Predictive Low Glucose Technology**
General Device Characteristic Similarities		
Intended Use/Indications For 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.	**Same**

	Predictive Low Glucose Technology is intended for single patient use and requires a prescription.	
Product Code	QJS	**Same**
Prescription Use	Prescription is required	**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**
Glucose Target (Target Settings)	100 mg/dL 110 mg/dL 120 mg/dL Temp Target: 150 mg/dL	**Same**
Auto Correction Bolus Target	120 mg/dL	**Same**
Meal / Food Bolus	Manual input of meal size for delivery of bolus either through blood glucose based insulin dose calculator or through iAGC	**Same**
Compatible Continuous Glucose Monitoring Systems	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Medtronic MiniMed Continuous Glucose Monitors (CGMs)	**Same**
General Device Characteristic Differences		

Intended Populations	Type 1 diabetes mellitus in persons 7 years of age and greater.	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
Compatible U-100 Insulins	Novolog® Humalog® Admelog®	Novolog® Humalog® Admelog® Lyumjev® Fiasp®
Alerts/Alarms	Compatible ACE pump displays algorithm-related alerts/alarms	MiniMed app will display alerts/alarms on user's smartphone or dedicated handheld device, or Compatible ACE pump displays algorithm-related alerts/alarms
Primary User Interface	ACE Pump	MiniMed app and ACE Pump
Bolus Calculator	Blood glucose insulin calculator embedded in 780G firmware	Predictive Low Glucose Technology contains a bolus calculator that calculates an insulin dose based on user-entered blood glucose data

V Standards/Guidance Documents Referenced:

- Medical devices - Application of risk management to medical devices
  ISO 14971 Third Edition 2019-12; 5-125

- Medical device software - Software life cycle processes
  IEC 62304 Edition 1.1 2015-06 Consolidated version; 13-79

- Medical Devices – Part 1: Application of usability engineering to medical devices
  IEC 62366-1 Edition 1.1 2020-06 Consolidated Version; 5-129

- Medical Devices – Information to be supplied by the manufacturer
  ISO 20417 First Edition 2021-04 Correction version 2021-12; 5-135

VI Performance Characteristics:

A. Non-Clinical Performance

Human Factors

Human Factors validation testing assessed users with either type 1 diabetes or type 2 diabetes with a total of 60 users tested across four distinct user groups and included independent users and dependent users with their caregiver. The users were assessed in using a complete system including a representative screenless ACE pump and the MiniMed App.

The users had a mix of insulin pump and automated insulin delivery experience and consisted of users currently on multiple daily injections of insulin, current users of the MiniMed 780G, and users who utilize other pumps or automated insulin delivery systems. Training was tailored to specific users' needs and consisted of both virtual training via video and training through a certified trainer that was trained by the manufacturer.

The results of the validation testing support that the subject device is substantially equivalent to the predicate.

B. Clinical Studies:

No new clinical data was provided for the changes reviewed in this submission.

See K253585 for the IFU expansion of SmartGuard and Predictive Low Glucose Technology to be used for the management of type 2 diabetes in persons 18 years of age and older requiring insulin, as well as for the addition of Fiasp and Lyumjev as compatible insulin products.

C. Other Supportive Device Performance Characteristics Data

Software:
The software documentation including risk management, software requirements, design specifications, lifecycle management, architecture, and unresolved anomalies supports substantial equivalence.

Cybersecurity:
The cybersecurity documentation supports substantial equivalence.

Predetermined Change Control Plan (PCCP):

The PCCP describes planned modifications to support interoperability of MiniMed iAGCs with future compatible connected devices, including:

1. Qualification and integration of new ACE pumps and new iCGMs
2. Updates to the MiniMed CareLink App to ensure continued compatibility with future interoperable devices
3. Continued maintenance of previously marketed and qualified ACE pumps, iCGMs, and the Patient App

The scope of the modifications are restricted to interoperability and some of the key modifications are as follows:

- One-Time Patient app software updates for iCGM integration such as:
    - NFC-activation and pairing for iCGM
    - Sensor change capability between compatible CGMs
    - BG-check UI updates for iCGM
    - Alert messaging and parameters for iCGM
    - Compatibility checking processes
- Future App updates:
    - Software updates for device integration
    - Support for multiple device configurations
- Requalification of previously marketed ACE Pumps, iCGMs, and patient apps

For new ACE pumps the method for implementing a modification is as follows:

- Assess compatibility with ACE Pump Compatibility and Performance Specifications
- Conduct risk analysis
- Complete software design integration and perform integration V&V testing
- Document qualification and integration evidence
- Release Risk Management Report
- Update labeling, notify users, and launch

For additions of new iCGMs the method for implementing the modification is as follows:

- Assess compatibility with iCGM Sensor Specifications and Compatibility/Performance Specifications
- Conduct risk management
- Conduct Virtual Patient Model Equivalency Testing (one-time establishment of acceptance criteria)
- Develop Sensor Error Model
- Conduct Virtual Patient Model Clinical Trial Testing (using pre-established acceptance criteria)
- Complete software design integration and perform integration V&V testing
- Document qualification and integration evidence
- Release Risk Management Report
- Update labeling, notify users, and launch

For previously marketed devices the process would be similar for respective ACE pump and iCGM qualification but would scale testing to assess impacted features only and potentially leverage previous testing where appropriate.

All changes via PCCP will be verified and validated per the following:

- Product Level Functional Verification Testing
- System Verification Testing
- Cybersecurity Testing (risk assessment and penetration testing)

- EMC and RF Wireless Testing
- Human Factors Validation

Finally, the changes implemented via the PCCP need to also follow an impact assessment as the changes cannot impact the intended use of the MiniMed iAGCs, therapy delivered remains equivalent to the predicate device, no new questions of safety and effectiveness are raised, and modifications should enhance flexibility and scalability while maintaining safety and clinical performance.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

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