510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253512

B Applicant

Medtronic MiniMed

C Proprietary and Established Names

MiniMed Go App

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 – Predictive pulmonary-function value calculator	Clinical Chemistry

E Purpose for Submission:

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The MiniMed Go app is indicated for people with diabetes or their caregivers. The indicated patient population varies based on the combination of connected CGM and injector.

Simplera sensor only: Diabetes patients ages 18 years and older

InPen smart insulin pen only: Diabetes patients ages 7 years and older, or younger patients under the supervision of an adult caregiver

Simplera sensor and InPen smart insulin pen: Diabetes patients ages 18 years and older

Instinct sensor and InPen smart insulin pen: Diabetes patients ages 7 years and older, or patients ages 2 to 6 years under the supervision of an adult caregiver

The dose calculator of the MiniMed Go app is indicated for the management of diabetes by people with diabetes for calculating an insulin dose based on user entered data, most recent glucose value and active insulin.

To calculate a recommended insulin dose, a healthcare professional must provide patient-specific therapy settings including glucose target, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.

For an insulin dose based on fixed or variable meal sizes, a healthcare professional must also provide patient-specific fixed doses or meal sizes to be programmed into the software prior to use.

When connected to a CGM, the app supports display of Sensor Glucose (SG) values and trend arrows. When connected to the InPen smart insulin pen, the app supports automatic logging of insulin doses, tracking of active insulin, and a dose calculator. The app also supports alerts or reminders for low glucose, high glucose, and insulin doses.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only.

- Follow the instructions and safety warnings in this user guide to receive alerts. Missing alerts from the app can result in undetected low and high glucose levels.
- Always use a BG meter reading to make treatment decisions if no sensor data are available or if symptoms do not match the SG value.
- Do not use the app if you have insufficient vision or hearing as you will need to verify alerts sent by the app.
- Do not use the app without understanding how the mobile device settings work. If any settings are changed, the app display and notification features may not work as intended, including not receiving SG alerts or status alerts.
- Make sure that your settings in the app are correct. Your healthcare professional should provide your therapy settings. Incorrect settings may result in incorrect recommendations which may result in hypoglycemia or hyperglycemia.
- Make sure Bluetooth is on, even if the mobile device is in airplane mode. If Bluetooth is off, the app will not send SG information or alerts.
- Do not force close the app. If the app is closed, the app will not send SG information or alerts.
- Check the app occasionally to make sure it is running. The mobile device may close the app automatically when another app is in use, such as a game. If the app is closed, the app will not send SG alerts.
- Always make sure to open the app after the mobile device restarts to ensure the app sends SG alerts.
- Turning off automatic updates on the mobile device may help to avoid unintentionally updating to an operating system that is not confirmed as compatible with the app.

- When power saving settings are enabled, the mobile device may delay the alerts and notifications from the app.
- Alerts for the app will sound through headphones when headphones are connected. If headphones are connected but they are not being used, SG alerts may not be heard.
- Always allow notifications for the app. If notifications are turned off, the app will not send any alerts, including the Urgent Low Alert.
- If alerts and reminders are disabled on the mobile device, you will not receive them, including the Urgent Low Alert.

III Device Description

The MiniMed Go App is a software-only mobile application intended to connect with compatible Continuous Glucose Monitors (CGMs) – including the Simplera Sensor (P160007/S047) and Instinct Sensor (K233537), and the InPen smart insulin injector (K242775). The App enables people with diabetes to manage their therapy through data visualization, insulin dose calculation, and event logging. The App can be installed on compatible mobile devices, enabling users to effectively manage their diabetes. The compatible devices include the user's Android/iOS mobile phones or the App Manager, a compatible display device configured to host Medtronic MiniMed applications.

The App Manager is a compatible display device configured to host Medtronic MiniMed applications. It can be used as an alternative to installation of MiniMed Go App on the user's personal compatible smartphone. The App Manager is a durable handheld medical device consisting of commercial off-the-shelf (COTS) Samsung smartphone hardware, with a Medtronic branded case, operating on the Android OS with MiniMed Go App pre-installed and configured for diabetes management use only. The App Manager is configured via a Mobile Device Management (MDM) service to lock down specified functionalities and to ensure that the App Manager is used solely as a medical device.

The App Manager is used in conjunction with the MiniMed Go App to facilitate communication with the InPen, Simplera sensor and Instinct sensor via COTS Samsung device's BLE and NFC connectivity. Its Wi-Fi connectivity is used to upload data to CareLink Cloud.

The App functions as the primary display and control interface for the InPen and connected CGM systems, consolidating device management, data visualization, and alert functions within a single software platform. It replaces the standalone CGM applications and serves as the central interface through which users manage connected devices and receive CGM, InPen and other system notifications. This integration provides a unified platform that supports diabetes therapy management and improves the overall user experience through consolidated device interaction.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

InPen App

B Predicate 510(k) Number(s):

K242775

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253512	K242775
Device Trade Name	MiniMed Go App	InPen App
General Device Characteristic Similarities		
Intended Use/Indications For Use	The MiniMed Go App is intended to manage diabetes by calculating insulin doses using user entered glucose value, logging the insulin doses administered by InPen and providing alerts and reminders. Additionally, the App is also intended to manage diabetes by directly connecting to compatible CGMs for display of SG values and trends and providing CGM related alerts and reminders.	Same
Prescription Use	Yes	Same
Environment of Use	Home	Same
Operating Systems	Android and iOS	Same
Communication with Insulin Pumps	No	Same
Control or Affect Insulin Delivery	No	Same
Insulin dose calculator	Allows users to calculate rapid-acting bolus doses using glucose level, anticipated meal intake (carb counting, fixed dose or meal estimation) and calculated active insulin to prevent insulin stacking. Active insulin display shows users how much rapid-acting insulin is remaining in their body from prior injections.	Same
General Device Characteristic Differences		
Compatible Medical Devices	InPen Smart Insulin Injector Simplera Sensor	InPen Smart Insulin Injector

	Instinct Sensor	
Sensor Glucose (SG) Readings	Obtained directly from connected CGMs and displayed on the landing page and retrospective graph.	Obtained from the cloud and displayed on the landing page and retrospective graph
Connection to CareLink	Data from all compatible devices is shared with CareLink cloud services.	The InPen App is not directly connected to CareLink; however, SG values are sent from CareLink to the InPen Cloud and subsequently the InPen App.
Compatible Medical Devices	InPen Smart Insulin Injector Simplera Sensor Instinct Sensor	InPen Smart Insulin Injector
App Controller	In addition to installation on user's compatible smart device, MiniMed Go App can also be used on a durable handheld medical device consisting of commercial off-the-shelf (COTS) Samsung smartphone hardware, with a Medtronic branded case, operating on the Android OS with MiniMed Go App pre-installed and configured for diabetes management use only.	InPen App can be installed on user's compatible smart device.

V Standards/Guidance Documents Referenced:

IEC 1162366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
Medical devices - Part 1: Application of usability engineering to medical devices

IEC 1162304 Edition 1.1 2015-06 CONSOLIDATED VERSION
Medical device software - Software life cycle processes

IEC 1182304-1 Edition 1.0 2016-10
Health software - Part 1: General requirements for product safety

ISO 1120417 First edition 2021-04 Corrected version 2021 -12
Medical devices - Information to be supplied by the manufacturer

ISO 1115223-1 Fourth edition 2021-07
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

VI Performance Characteristics:

A. Non-Clinical Performance

Not applicable.

B. Clinical Studies:

Not applicable.

C. Other Supportive Device Performance Characteristics Data

Usability:
The sponsor provided comprehensive human factors engineering protocols and study results demonstrating that intended users can safely and effectively perform all critical tasks associated with the modified device features. The study participants were representative of the device's intended user population, including:

User Group 1: Adult Type 1 Diabetes (n=17)

- Age Range: 19-69 years (Average: 38.4 years)
- CGM Experience: 14 experienced, 3 naive
- Independence Level: 14 fully independent, 3 caregiver dyads
- Device Distribution: 8 iOS, 9 Android

User Group 2: Adult Type 2 Diabetes (n=16)

- Age Range: 36-80 years (Average: 59.6 years)
- CGM Experience: 14 experienced, 2 naive
- Independence Level: 11 fully independent, 5 caregiver dyads
- Device Distribution: 8 iOS, 8 Android

User Group 3: Pediatric Participants (n=17)

- Age Range: 4-17 years (Average: 11.7 years)
- CGM Experience: All 17 experienced, 0 naive
- Dependency Levels:
    - 5 Fully dependent (require complete assistance)
    - 9 Partially dependent (require some assistance)
    - 2 Fully independent (manage tasks without assistance)
- Device Distribution: 9 iOS, 8 Android

The human factors validation studies adequately demonstrated that users could operate the device safely without use-related errors that could compromise patient safety or treatment effectiveness. The results support a determination of substantial equivalence to the predicate device regarding usability and user interface design.

Software:
The sponsor provided comprehensive software documentation in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The documentation was consistent with the requirements for

software classified as having a major level of concern, reflecting the device's potential impact on patient safety through insulin dosing recommendations.

The software documentation package included appropriate:

- Software requirements and design specifications demonstrating traceability between intended use and software functionality
- Verification and validation protocols with evidence of comprehensive testing across anticipated use scenarios
- Risk analysis and mitigation strategies addressing potential software-related hazards and their clinical implications
- Cybersecurity considerations appropriate for the device's connectivity and data handling capabilities

The submitted software documentation was determined to be acceptable and sufficient to support the safety and effectiveness determination for this 510(k) submission.

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.