January 8, 2026

Medtronic Minimed
Ajay Aluru
Principal Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 92883

Re: K253512
Trade/Device Name: MiniMed Go App
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC
Dated: November 5, 2025
Received: November 6, 2025

Dear Ajay Aluru:

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.

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.

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
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253512

Device Name
MiniMed Go app

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) Summary
MiniMed Go App

510(k) Submitter Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Ajay Aluru Principal Regulatory Affairs Specialist Medtronic MiniMed Inc. ajay.aluru@medtronic.com
Alternate Contact Person	Shivani Shah Senior Regulatory Affairs Specialist Medtronic MiniMed Inc. shivani.a.shah@medtronic.com
Date Prepared	Oct 15, 2025

Device Information

Device Trade Name	MiniMed Go App
Device Classification Name	Predictive pulmonary-function value calculator
Regulation Number	21 CFR § 868.1890
Product Codes	NDC
Device Panel	Clinical Chemistry
Device Class	Class II

Predicate Device Information

Product Code	Predicate Device
NDC	InPen System App (**K242775**)

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 and Instinct Sensor, and the InPen smart insulin injector. 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 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.

Indications for Use / Intended 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.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The features of the subject device and predicate device are compared in **Table 1-1**

Table 1-1: Substantial Equivalence Table

	Predicate Device **K242775** **InPen System App**	**Subject Device** **MiniMed Go App**
Manufacturer	Medtronic MiniMed	**SAME**
Device Classification	Class 2	**SAME**
Product Code	NDC	**SAME**
Regulation	868.1890 – Predictive pulmonary-function value calculator	**SAME**
Intended Use	The InPen App is intended to manage diabetes by calculating insulin doses using user entered glucose values or SG values (sourced from the cloud; no direct CGM connectivity), logging the insulin doses administered by InPen and providing alerts and reminders.	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.
Indications for Use	The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient aged 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data. For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use. For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed	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

	Predicate Device K242775 InPen System App	Subject Device MiniMed Go App
	doses/ meal sizes to be programmed into the software prior to use.	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.
Prescription Use	Yes	**SAME**
Environment of Use	Home Use	**SAME**
Principle of Operation	The InPen App uses Bluetooth capability of compatible smart device to connect with InPen. Insulin doses are calculated using a manual entry of glucose value or auto populated SG value that is sourced from cloud server through an active internet connection. CGMs cannot be directly connected to the App.	The MiniMed Go App uses Bluetooth and NFC capability of compatible smart device to connect with compatible CGMs and InPen. Insulin doses are calculated using manual entry of glucose values.
Operating Systems	Android and iOS	**SAME**
Compatible Medical Devices	InPen Smart Insulin Injector	InPen Smart Insulin Injector Simplera Sensor Instinct Sensor

	Predicate Device **K242775** **InPen System App**	**Subject Device** **MiniMed Go App**
Sensor Glucose (SG) Readings	Obtained from the cloud and displayed on the landing page and retrospective graph	Obtained directly from connected CGMs and displayed on the landing page and retrospective graph.
Connection to CareLink	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.	Data from all compatible devices is shared with CareLink cloud services.
Communication with Insulin Pumps	No	**SAME**
Control or Affect Insulin Delivery	No	**SAME**
Wireless Connectivity	InPen – Bluetooth InPen Cloud – Wi-Fi/Cellular	InPen – Bluetooth Simplera Sensor – Bluetooth Instinct Sensor – NFC and Bluetooth CareLink – Wi-Fi/Cellular
Insulin dose logging	Manual for rapid and long-acting insulin. Auto logging of rapid-acting insulin from InPen injector.	**SAME**
Therapy Settings: Carb Ratio	Allowable range 1-300 g/unit in 0.1 g/unit increments	Allowable range 1-200 g/unit in: 0.1 g/unit increments for 1-9.9 g/unit 1 g/unit increments for 10-200 g/units
Therapy Settings: Insulin Sensitivity Factor	1-600 in 0.1 mg/dL/unit increments	1-400 in 1 mg/dL/unit increments
Therapy Settings: Target Glucose Range	70-200 mg/dL in 1-unit increments	60-250 mg/dL in 1-unit increments
Therapy Settings: Active Insulin Time	2-8 hours in 15 min increments	**SAME**
Therapy Settings: Recommended Dose	2-60 units in 1-unit increments	**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	**SAME**

	Predicate Device **K242775** **InPen System App**	**Subject Device** **MiniMed Go App**
	how much rapid-acting insulin is remaining in their body from prior injections.	
Meal Therapy Types	Carb Counting Meal Estimation Fixed Dose	**SAME**
Alarms/Alerts	Correct high glucose Missed dose Long-acting dose reminder Scheduled reminders Security related InPen Injector device status Mobile device status	Urgent low sensor glucose Alert on low/high Alert before low/high Fall alert Rise alert Correct high glucose Missed dose Long-acting dose reminder Security related InPen Injector device status Sensor device status Mobile device status
App Controller	InPen App can be installed on user's compatible smart device.	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.

Summary of Non-Clinical Performance Data

Medtronic MiniMed conducted extensive performance bench testing to demonstrate substantial equivalence to the predicate device:

- **Software Testing -** A software verification process was performed on the MiniMed Go App in accordance with EN IEC 62304:2015, "Medical device software – Software life cycle processes." The verification activities included unit testing, integration testing, system testing, and traceability verification to ensure that software requirements were correctly implemented and that software outputs met design specifications. The results of the verification demonstrated that the software functions as intended, performs reliably under defined conditions, and meets the applicable safety and performance requirements for its intended use, users, and operating environments.
- **Cybersecurity Assessment and Testing** - The cybersecurity activities for the MiniMed Go App were all completed per the 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. The information relating to the penetration testing conducted as part of MiniMed Go App cybersecurity evaluation and software bill of materials was provided.
- **Shelf-Life Testing -** Shelf Life of the App Manager was determined based on the battery life. It was concluded that the Shelf-Life is 12 months based on the rationale that the App Manager will retain no less than 20% battery capacity after 12 months in a powered-off state within the distribution center.
- **Biocompatibility -** The App Manager has been evaluated for biological safety in accordance with ISO 10993-1 and FDA 2023 guidance. Based on the results of the testing, it can be concluded that the App Manager is biocompatible and safe for its intended use.
- **Electromagnetic Compatibility (EMC) -** Testing of the MiniMed Go App was conducted in accordance with IEC 62368-1. All tests were successfully passed, demonstrating that the App meets the required EMC performance criteria for its intended use and operating environment.
- **Human Factor and Usability Testing** - A human factors and usability engineering process was performed on MiniMed Go App with compatible Medtronic CGMs 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 -** The IFU was assessed according to defined quantitative readability acceptance criteria.

All tests passed and the results demonstrate that technological differences do not raise additional concerns of safety and effectiveness.

Risk Management

Risk management was completed in accordance with ISO 14971: 2019. Risk control measures identified for each hazard were implemented and verified to be effective at reducing risk. Verification activities, as required by risk analysis, demonstrated that the predetermined acceptance criteria were met, and the device is safe for use. All risks have been reduced as far as possible. The benefit-risk analysis has determined that the benefits of using the device outweigh the residual risk, and the overall residual risk is acceptable.

Conclusion

Based on the information provided in this Traditional 510(k), Medtronic MiniMed concludes that the subject device, MiniMed Go App, is substantially equivalent to the predicate device, InPen System App (K242775) for the Product Code NDC.