



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K242775

B Applicant

Medtronic MiniMed

C Proprietary and Established Names

InPen System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	Clinical Chemistry (75)

E Purpose for Submission:

Addition of new “correct high glucose” and “missed dose” alert functionalities to the InPen App. The InPen App is a component of the InPen System.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The InPen System is a home-use reusable pen for single-patient use by people with diabetes under the supervision of an adult caregiver, or by a patient aged 7 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges, Novo Nordisk Novolog® U-100 3.0 mL cartridges, and Novo Nordisk Fiasp® U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen Smart Insulin pen allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

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 doses/ meal sizes to be programmed into the software prior to use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The insulin dose calculations provided by this device are meant for patients undergoing multiple daily injection (MDI) therapy.

III Device Description

The InPen System consists of the InPen Smart Insulin Pen, the InPen App (which runs under an iOS or Android operating system), and the InPen Cloud.

The InPen App is designed to manage the wireless transfer of insulin dose data from the InPen, log insulin dose data, and provide a dose calculator to aid mealtime insulin dose calculations. The insulin dose calculations provided by the app are meant for patients undergoing multiple daily injection (MDI) therapy.

The App features a dose calculator that calculates the applicable dose of rapid-acting insulin based on information provided by the user (e.g., amount of carbohydrates in meals/meal type, current glucose levels, etc.) and current active insulin calculated (based on the time and amount of the last dose of rapid-acting insulin). The dose calculator can calculate the required insulin volume three different ways, namely: fixed dosing, meal estimation, or carbohydrate counting.

To get started, the user downloads and opens the App on a smart phone with either an iOS or Android operating system, creates an account, and follows the set-up steps within the set-up wizard. Once the user is logged in, the dose calculator and Long-Acting insulin settings prescribed by the healthcare provider (HCP) are entered. The three different methods include:

- Fixed Dosing
- Meal Estimation
- Carbohydrate Counting

As part of the set-up, the user pairs the InPen Smart Insulin Pen to the App prior to use. Once paired, the user can follow the video instructions in the App on the following subjects:

- Installing an insulin cartridge
- Taking an Insulin Dose

- Printing Reports
- Setting Notifications and Alerts
- Using the App

The App includes a logbook feature that displays the patient's recent activity related to glucose values, meal types and sizes, dose calculations, doses by insulin type (rapid- or long-acting), cartridge replacement, and priming. Doses taken using the InPen Smart Insulin Pen are automatically received by the App and logged within the logbook, but the user can also manually log doses if needed. The App and Smart Insulin Pen are synchronized so that doses made while the App is disconnected, e.g., airplane mode or while Wi-Fi is unavailable are added upon reconnection.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

InPen System

B Predicate 510(k) Number(s):

K201337

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K242775</u>	<u>K201337</u>
Device Trade Name	InPen System	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	<p>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 age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data.</p> <p>For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target</p>	

	<p>blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.</p> <p>For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.</p>	
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Same
Communication with insulin pumps	No	Same
Control or affect glucose measurements	No	Same
Control or affect insulin delivery	No	Same
Reports, graphs, and Electronic Logbook	Yes	Same
Insulin Dose Calculator	Calculates insulin doses for meals and corrections while accounting for insulin on board	Same
Carbohydrate Calculator	Calculates carbohydrate intake based on user-entered data	Same
General Device Characteristic Differences		
InPen Cloud Communication with Carelink Cloud to receive Medtronic CGM glucose measurements	Can receive the Medtronic CGM sensor glucose measurements in real time (every 5-minutes) from the Carelink Cloud. The CGM data can be displayed and printed in therapy reports by	Can receive the most recent CGM glucose measurements from the Carelink Cloud. The CGM data can be viewed on the InPen App for the user and in

	the HCP and user from the InPen App and InPen Cloud. In addition to the existing time-based alerts, the user can select CGM based alerts for missed dose and correct high glucose.	therapy reports generated by the InPen Cloud for the HCP and the user.
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V Standards/Guidance Documents Referenced:

ANSI AAMI ISO 14971: 2019, Medical Devices- Application of risk management to medical devices

ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

VI Performance Characteristics:

A. Analytical Performance

Not applicable.

B. Other Supportive Instrument Performance Characteristics Data

Usability

Assessment of the changes to the InPen App and InPen Cloud occurred through a Human Factors summative usability evaluation. In the summative evaluation, patients completed self-training and then used the InPen App and InPen Cloud to perform a series of critical tasks involving the use of the InPen App and Cloud, including the additional alerts and reminder. Subjects were representative of the device's intended use population, including adults, caregivers, independent pediatrics, and dyads (parent and child) with or without diabetes experience. The results of this study were adequate to demonstrate safe use of the device and support substantial equivalence to the predicate.

Software

Software regression testing was conducted in accordance with established specifications and documentation was provided as recommended by FDA Guidance "Content of Premarket Submissions for Device Software Functions", published June 14, 2023. The test results met acceptance criteria and support that the subject device is acceptable for its intended use.

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.