November 12, 2024

Medtronic MiniMed
Ty Cowart
Senior Principal Regulatory Specialist
18000 Devonshire Street
Northridge, California 92325

Re: K242775
Trade/Device Name: InPen System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: September 13, 2024
Received: September 13, 2024

Dear Ty Cowart:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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)*
K242775

Device Name
InPen System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. 510(k) Summary

1.1. InPen App

Table 1-1: General Information

Name of Device	InPen System
Common Name	Pen Injector with Dose Calculator
Predicate Device Name and Model ID	InPen™ System (MMT-8060/MMT-8061)
Predicate 510(k) Number	K201337
Classification Name	Class II Piston syringe with Drug Dose Calculator
Product Code	FMF, NDC
Classification Regulation	21 CFR 868.1890; 21 CFR 880.5860
Manufacturer and Design Facility	Medtronic MiniMed, Inc. 12230 World Trade Drive, Suite 100 San Diego, California 92128
Manufacturing Facility	Jabil Circuit De Chihuahua Av. Alexandro Dumas 11341 Complejo Industrial Chihuahua Chihuahua, MX 31136
Establishment Number	3004060780
Primary Contact Information	Ty Cowart Senior Principal Regulatory Affairs Specialist Tel: 678-481-9246 Email: **ty.cowart@medtronic.com**
Secondary Contact Information	Christina Rowe Senior Regulatory Affairs Manager Tel: (818) 942-4875 Email : **christina.rowe@medtronic.com**

2. Device Description

2.1. InPen App

The InPen App is a software application with versions that are compatible with mobile phones running the iOS or Android operating system. The App is a component of the InPen

system and is used with the InPen Smart Insulin pen for the management of insulin-requiring diabetes. The InPen App communicates with the InPen Smart Insulin pen to communicate doses that are delivered by the user. The InPen App is also compatible for use with blood glucose (BG) meters, Medtronic Continuous Glucose Monitors (CGMs), and the Dexcom CGMs. The InPen App includes a dose calculator that can calculate and recommend a dose for the user to review and consider as part of following the treatment plan prescribed by the healthcare provider. The dose calculator features in the App require that a healthcare professional provide patient-specific values for various therapy settings for programming into the App prior to use by the patient. These therapy settings include glucose target(s), duration of insulin action time, insulin sensitivity factor(s), and insulin-to-carbohydrate ratio(s) or fixed insulin doses for meal types and sizes. The dose calculator feature is unavailable to the user until these patient-specific values, provided by the healthcare professional, are programmed and an InPen has been paired to the App. A healthcare provider may also provide long-acting insulin settings to be programmed into the InPen App. The App includes a logbook feature that displays the patient's recent activity related to BG values, meal types and sizes, dose calculations, doses by insulin type (rapid- or long-acting), cartridge replacement and priming. The App also provides reminders and alerts that can notify the user to check their glucose, dose insulin (for potential missed meals, correction doses, and long-acting insulin doses) and log doses according to schedule, replace a cartridge, or if the insulin pen has been exposed to very low or very high temperatures. The App can generate a supplemental summary report of recent therapy information for review by the patient or healthcare professional (HCP).

2.2. The InPen Cloud

The InPen Cloud includes a therapy report component that the user and the health care provider (HCP) can view and print to assess the overall diabetes control and treatment plan. The report displays data based upon user and HCP-defined inputs, such as glucose, insulin and carb trended information, during the defined period, as well as dose calculator usage and alerts and reminders. The Insulin Notification Service (INS) is a subcomponent of the InPen Cloud that can receive Medtronic CGM sensor glucose measurements from the CareLink Cloud. The INS includes two algorithms that assess "real time" sensor glucose measurements to identify whether a user has missed a dose or if their glucose is rising and a correction dose is needed. If either of these conditions exist, a silent notification is sent by the INS to the InPen App. The InPen App confirms the data and can provide an audible and visual alert to

the user. The user can act on the alert by assessing their glucose levels followed by calculating a dose utilizing the InPen App dose calculator.

3. Indications For Use

The current Indications for Use statement is provided below:

The InPen System is a home-use reusable pen injector for single-patient use by people with diabetes under the supervision of an adult caregiver, or by a patient age 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 injector 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 age 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.

4. Technological Characteristics and Substantial Equivalence (SE)

InPen App Attributes	**Predicate Device InPen System (K201337)**	**Subject Device InPen System**	**Comparison**
Classification	(Class II - NDC - 21 CFR §868.1890)	(Class II - NDC - 21 CFR §868.1890)	Same
Indications For Use	The InPen System is a home-use reusable pen injector for single-patient use by people with diabetes under the supervision of an adult caregiver, or by a	The InPen System is a home-use reusable pen injector for single-patient use by people with diabetes under the	Same

InPen App Attributes	**Predicate Device** InPen System (K201337)	**Subject Device** InPen System	Comparison
	patient age 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 injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments. The InPen System 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. 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.	supervision of an adult caregiver, or by a patient age 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 injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments. The InPen System 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. 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.	
Prescription Use	Yes	Yes	Same

InPen App Attributes	**Predicate Device** InPen System (K201337)	**Subject Device** InPen System	Comparison
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Same
Communication with insulin pumps	No	No	Same
Software Level of Concern	Major	Major	Same
Wireless Connectivity	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same
Control or affect glucose measurements	No	No	Same
Control or affect insulin delivery	No	No	Same
Reports, graphs, and Electronic Logbook	Yes	Yes	Same
Meal Size Entry	Grams of carbohydrates	Grams of carbohydrates	Same
Fixed Dose Setting	Set by User	Set By User	Same
Insulin Dose Calculator	Calculates insulin doses for meals and corrections while accounting for insulin on board	Calculates insulin doses for meals and corrections while accounting for insulin on board	Same
Carbohydrate Calculator	Calculates carbohydrate intake based on user-entered data	Calculates carbohydrate intake based on user-entered data	Same
Manual Dose Entry	Yes	Yes	Same
InPen Dose Entry	Yes	Yes	Same
Tracking of residual bolus insulin to mitigate stacking	Yes	Yes	Same
Operating platform	Android and iOS platforms	Android and iOS platforms	Same
UI Standards	Android and iOS standards	Android and iOS standards	Same
InPen Cloud Communication with Carelink Cloud to receive Medtronic CGM glucose measurements	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 therapy reports generated by the InPen Cloud for the HCP and the user.	Can receive the Medtronic CGM sensor glucose measurements in real time (every 5minutes) from the Carelink Cloud. Two software algorithms have been added to the InPen Cloud that include computational methods to identify whether a user has missed an insulin dose or if their glucose is rising. If	Addition of two algorithms in the InPen Cloud (Insulin Notification Service) to identify and send a silent notification to the InPen App. Two new visual and audible alerts have been added to the InPen App to alert the user to the presence of a missed insulin dose or when their glucose level is high.

InPen App Attributes	Predicate Device InPen System (K201337)	Subject Device InPen System	Comparison
		either of these conditions exist, a silent notification is sent to the InPen App. The InPen App confirms the data and is responsible for providing an audible and visual alert to the user. The CGM data can be displayed and printed in therapy reports by the HCP and user from the InPen App and InPen Cloud.	
Long-Acting Dose Reminder	An optional user-enabled alert which is provided to the user. User sets a time when their prescribed Long- Acting Insulin is taken. If the Long-Acting Dose is not taken, the App will present a visual reminder to the user dose is not taken by the user.	An optional user-enabled audible and visual reminder which is provided to the user. The alert's status has been changed to allow its presentation to be active if the phone volume is turned down or in a Do Not Disturb Mode. If the Long-Acting Dose is not taken, the App will present an audible and visual reminder to the user.	Improved the existing Long-Acting Reminder to include both an audible and visual alert.
Missed Dose Alert	A user enabled missed dose reminder is currently available to the user and is a time-based meal reminder. The user configures their meal-time window for each meal type (breakfast, lunch, dinner). If the alert is enabled by the user an alert is supplied if no insulin dose was logged within the user set meal-time window.	A user-enabled missed dose alert (audible and visual) for users of the InPen System and a Medtronic CGM. The InPen App will alert the user when their sensor glucose level indicates that a missed insulin dose has occurred. Non-CGM users or CGM users who do not enable the alert can choose to enable and receive the existing missed dose reminder.	A user enabled Alert added as an option for users of a Medtronic CGM.
Correct High Glucose Alert	A user enabled alert that reminds the user to check their glucose level 2 hours after a dose and check their glucose level before their bedtime. After checking their glucose and if their glucose is high, the user can use the dose calculator to obtain a dose recommendation.	A user-enabled Correct High alert for users of the InPen System and a Medtronic CGM. The InPen App will alert the user when their glucose is rising high and is above the default value of 180 md/dL. Non-CGM users or CGM users who do not enable the alert can choose to enable and receive the existing reminders to check their	A user enabled Alert added as an option for users of a Medtronic CGM.

InPen App Attributes	**Predicate Device** InPen System (K201337)	**Subject Device** InPen System	Comparison
		glucose level 2 hours after a dose and before their bedtime.	

5. Performance Data

Software verification and validation testing was performed in accordance with the FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions", and FDA's guidance "General Principles of Software Validation". Verification and validation activities included software testing consisting of unit level testing, integration level testing, and systems testing of the InPen App and InPen Cloud.

Cybersecurity Testing was performed to assess data integrity to ensure that data remains consistent and accurate. Cyclic redundancy checks (CRC) were used for all data transmissions and stored dose records.

As part of the evaluation, risk management activities in accordance with ISO 14971: 2019 Medical Devices-Application of risk management to medical devices, were undertaken, including a risk management plan, risk assessment, and a risk management report.

Additional assessment of the changes to the InPen App and InPen Cloud occurred through a summative usability evaluation. In the summative evaluation, patients with sufficient diabetes knowledge 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.

5.Substantial Equivalence Conclusion

Based on the 510(k) Summary and information provided herein, Medtronic concludes that the subject device, InPen App and InPen Cloud (K201337) is substantially equivalent to the predicate InPen App (K201337) in its intended use, safety, effectiveness, and underlying scientific and operating principles. The proposed enhancements to the existing alerts of the InPen App do not raise additional questions or concerns for the safety and efficacy of the products that are included in this submission.

6. Conclusions

The subject device is considered substantially equivalent to the predicate device, as demonstrated by verification and validation data while maintaining the same intended use, technological characteristics, and principles of operation.