



January 15, 2026

Medtronic Minimed, Inc.
Amber Street
Senior Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 91325

Re: K253470

Trade/Device Name: MiniMed 780G Insulin Pump
Regulation Number: 21 CFR 880.5730, 868.1890
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: October 10, 2025
Received: October 10, 2025

Dear Amber Street:

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.

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

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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253470

Device Name

MiniMed 780G insulin pump

Indications for Use (Describe)

The MiniMed 780G insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The MiniMed 780G insulin pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The MiniMed 780G insulin pump contains a bolus calculator that calculates an insulin dose based on user-entered data.

The MiniMed 780G insulin pump is indicated for use in individuals 7 years of age and older.

The MiniMed 780G insulin pump is intended for single patient use and requires a prescription.

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.

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510(K) Summary MiniMed 780G Insulin Pump

510(k) Submitter Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Amber Street Senior Regulatory Affairs Specialist Medtronic MiniMed Inc. amber.n.street@medtronic.com
Alternate Contact Person	Felicia Haynes, PhD Senior Regulatory Affairs Manager Medtronic MiniMed Inc. felicia.a.haynes@medtronic.com
Date Prepared	Jan 14, 2026

Device Information

Device Trade Name	MiniMed 780G Insulin Pump
Device Common Name	Alternate Controller Enabled Insulin Infusion Pump (ACE Pump)
Device Classification Name	Alternate Controller Enabled (ACE) Insulin Infusion Pump, Calculator, Drug Dose
Regulation Number	21 CFR 880.5730, 21 CFR 868.1890
Product Codes	QFG, NDC
Device Panel	Clinical Chemistry
Device Class	Class II

Predicate Device Information

Product Code	Predicate Device
QFG	MiniMed 780G Insulin Pump (K251032)
NDC	InPen Dose Calculator (K242775)

Device Description

The MiniMed 780G insulin pump (“780G ACE Pump”) is an alternate controller enabled (ACE) pump intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. It can reliably and securely communicate with compatible digitally connected devices, including an integrated continuous glucose monitor (iCGM), interoperable Medtronic continuous glucose monitor (CGM), and interoperable automated glycemic controller (iAGC). The pump is intended to be used both alone and in conjunction with compatible, digitally connected medical devices for the purpose of drug delivery.

The 780G insulin pump is an ambulatory, battery-operated, rate-programmable micro-infusion pump that contains pump software and houses electronics, a pumping mechanism, a user interface, and a medication reservoir within the same physical device. The pump also contains a bolus calculator that calculates an insulin dose based on user-entered data. It is comprised of several discrete external and internal components including a pump case made of a polycarbonate blend, an electronic printed circuit board assembly stacks and a drive motor system.

The 780G Pump is an interoperable device that can communicate via a *Bluetooth Low Energy (BLE) wireless electronic interface* with digitally connected devices. The 780G pump is a host device for the iAGC and integrates iAGC algorithm into the pump firmware. The pump is then able to receive, execute, and confirm commands from an iAGC to adjust delivery of insulin. The pump receives sensor glucose (SG) data via BLE interface from a compatible iCGM or a compatible interoperable Medtronic CGM and transmits these CGM data to the embedded iAGCs.

The 780G pump can operate in one of two modes: Manual Mode or Auto Mode (also referred to as “SmartGuard Mode”). The pump provides the user with keypad pump controls, as well as a data screen for configuring therapy settings and viewing continuous real-time glucose values, glucose trends, alerts, alarms, and other information. The user interface and alerts provide the user with the ability to interact with the pump delivery system and digitally connected devices.

Indications for Use / Intended Use

The MiniMed 780G Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The MiniMed 780G Insulin Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The MiniMed 780G Insulin Pump contains a bolus calculator that calculates an insulin dose based on user-entered data.

The MiniMed 780G Insulin Pump is indicated for use in persons 7 years of age and older.

The MiniMed 780G Insulin Pump is intended for single patient use and requires a prescription.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The two (2) tables below provide a side-by-side comparison of the subject device, MiniMed 780G Insulin Pump compared to its predicate device for each Product Code: QFG and NDC.

ACE Insulin Pump (Product Code: QFG):

	Predicate Device MiniMed 780G Insulin Pump (K251032)	Subject Device MiniMed 780G Insulin Pump
Manufacturer	Medtronic MiniMed Inc.	Medtronic MiniMed Inc.
Device Trade Name	MiniMed 780G insulin pump	MiniMed 780G insulin pump
Device Classification	Class II	SAME
Product Code	QFG	SAME
Device Type/Regulation	Alternate Controller Enabled Infusion Pump (under 21 CFR 880.5730)	SAME

	Predicate Device MiniMed 780G Insulin Pump (K251032)	Subject Device MiniMed 780G Insulin Pump
Indications for Use/Intended Use	The MiniMed 780G Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The 780G Insulin Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The 780G Insulin Pump is indicated for use in persons 7 years of age and older. The 780G Insulin Pump is intended for single patient use and requires a prescription.	SAME
Prescription Use	Prescription is required	SAME
Environment of Use	Professional healthcare facilities and home environments	SAME
Patient Environment	On-body wearable ambulatory pump	SAME
Age Limitations	7 years and older	SAME
Glucose Target (Target Range Settings)	The MiniMed 780G pump dynamically adjusts to target the following glucose setpoints: 100 mg/dL (5.6 mmol/L) 110 mg/dL (6.1 mmol/L) 120 mg/dL (6.7 mmol/L)	SAME
Technological Characteristics	The MiniMed 780G ACE pump is an ambulatory, battery-operated, rate-programmable micro-infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device houses electronics, a pumping mechanism, a user interface, and a medication reservoir to deliver patient-programmed basal rates and boluses through an infusion set into the subcutaneous tissue.	SAME
Intended Population	Persons with diabetes mellitus ages 7 and up	SAME
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog® Admelog®	U-100 insulin: Novolog® Humalog® Admelog® Fiasp® Lyumjev®

	Predicate Device MiniMed 780G Insulin Pump (K251032)	Subject Device MiniMed 780G Insulin Pump
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient based on healthcare provider recommendations.	SAME
Insulin Delivery Modes	Both basal and bolus	SAME
Pump Operating Modes	Manual Mode Auto Mode	SAME
Insulin Basal Rate Delivery Range	0 – 35 U/hour	SAME
Insulin Delivery Profiles (Basal and Bolus)	8	SAME
Insulin Bolus Delivery Range	Minimum bolus: 0.025 units Maximum bolus: 25 units	SAME
Bolus Increments (Bolus Resolution)	0.025 units	SAME
Basal Delivery Accuracy (per 60601-2-24)	±5% Intermediate basal delivery (1 UPH) must meet ±5% of expected	SAME
Bolus Delivery Accuracy (per 60601-2-24)	±5% Delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.	SAME
Bolus Canceling	Supports bolus cancellation	SAME
Active insulin (IOB)	Programmable active insulin duration	SAME
Active insulin (IOB) tracking	Pump keeps track of the amount of active insulin from food and correction boluses (insulin on board, IOB) to prevent insulin stacking	SAME
Pump Device Accessories	MiniMed Mobile App (optional accessory, secondary display, Class II 510k-exempt) Compatible FDA cleared infusion sets (Class II) Compatible FDA cleared reservoirs (Class II) Belt Clip (non-medical device) Pump Covers/Cases (non-medical device)	SAME
Compatible Interoperable Devices	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Automated Glycemic Controllers (iAGCs)	SAME

	Predicate Device MiniMed 780G Insulin Pump (K251032)	Subject Device MiniMed 780G Insulin Pump
	Compatible Interoperable Medtronic Continuous Glucose Monitors (CGMs)	
Communication with Compatible Interoperable Devices	Bluetooth Low Energy (BLE)	SAME
Compatible Blood Glucose Meters	Commercially available BG meters that meet ISO 15197:2013	SAME
Alarm Type(s)	Visible, audible, vibratory	SAME
Pump Notifications, Alerts, Alarms, and Reminders Visible to User	The following are visible on the pump: <ul style="list-style-type: none"> • Reminders • Alerts • Alarms • Notifications 	SAME
Logging Records of Critical Events	Critical events logged by the system include: <ul style="list-style-type: none"> • A record of all drug delivery • A record of all user/therapy settings and changes to those settings • Device malfunctions • Alarms and alerts and associated acknowledgements • Connectivity events (e.g., establishment or loss of communications) 	SAME
Battery Type/ Power Requirements	The pump requires one AA (1.5V) battery	SAME
Pump Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% relative humidity	SAME
Pump Storage Conditions	Temperature: -4°F (-20°C) to 122°F (50°C) Humidity: 20% to 90% R relative humidity	SAME
Moisture Protection	IPX8: Protected against immersion in water up to 8 feet (2.4 meters) for up to 30 minutes	SAME
Pump Screen/Controls	Liquid Crystal Display (LCD) Screen + Keypad	SAME

	Predicate Device MiniMed 780G Insulin Pump (K251032)	Subject Device MiniMed 780G Insulin Pump
Wireless control of bolus insulin therapy	The 780G insulin pump does not have the capability to wirelessly control bolus insulin delivery via a mobile app.	SAME

Bolus Calculator (Product Code: NDC)

	Predicate Device InPen Dose Calculator (K242775)	Subject Device MiniMed 780G Insulin pump
Manufacturer	Medtronic	SAME
Device Trade Name	InPen Dose Calculator	MiniMed 780G Insulin pump
Device Type	Predictive Pulmonary-Function Value Calculator (under 21 CFR 868.1890)	SAME
Device Classification	Class II	SAME
Product Code	NDC	SAME
Prescription Use	Prescription is required	SAME
Operating Environment	Home Use	Professional healthcare facilities and home environments
Indications for Use/Intended Use	<p>The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes age 7 and older by calculating an insulin dose or carbohydrate intake based on user entered data.</p> <p>The device is indicated for use with Fiasp, NovoLog®, or Humalog® U-100 insulin.</p> <p>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.</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>	The 780G Pump contains a bolus calculator that calculates an insulin dose based on user-entered data.

	Predicate Device InPen Dose Calculator (K242775)	Subject Device MiniMed 780G Insulin pump
Therapy Type	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with insulin pump therapy in which calculator is integrated
Age Indication	Ages 7 and up	SAME
Specific Drug/Biological Use	U-100 insulin: NovoLog® Humalog® Fiasp®	U-100 insulin: Novolog® Humalog® Admelog® Fiasp® Lyumjev®
Principles of Operation	Calculate insulin doses for meals and corrections while accounting for active insulin (insulin on board).	SAME
Carbohydrate Calculator	Calculation based on either user-entered carbohydrate, meal size estimation, or fixed meal doses.	Calculates carbohydrate intake based on user-entered data.
Manual Data Entry	Yes	SAME
Requires BG for calculation	Yes	SAME
Operating Platform	Android and iOS	Pump firmware

Summary of Non-Clinical Performance Data

Medtronic conducted extensive performance bench testing for MiniMed 780G Insulin Pump to demonstrate substantial equivalence to the predicate device and to ensure that the subject device meets all applicable ACE Special Controls requirements defined in 21 CFR 880.5730. These are summarized below:

Delivery Volume Accuracy

Refer to **K251032**.

Catheter Occlusion Detection

Catheter Occlusion Detection testing for the 780G insulin pump was conducted with - Humalog, NovoLog, Admelog, Fiasp and Lyumjev U-100insulins to demonstrate the incidence of catheter blockage due to insulin crystallization. The test results confirmed that there were no pump

malfunctions or infusion set occlusions. The data for testing conducted with Humalog,Novolog and Admelog insulins can be found in **K251032**.

Drug Stability and Compatibility

Drug stability and compatibility testing was performed with U-100 insulins (Humalog, NovoLog, Admelog, Fiasp and Lyumjev) used with the 780G insulin pump. The test results demonstrated that the 780G insulin pump does not adversely affect the insulins being delivered, and that the insulin types do not adversely affect the pump. The data for testing conducted with Humalog,Novolog and Admelog insulins can be found in **K251032**.

Data Logging

The 780G insulin pump has been tested and verified for logging or recording timestamped critical events as required by the ACE pump special controls.

Cybersecurity

The cybersecurity activities for the 780G Insulin Pump were all completed per 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 780G Insulin Pump's cybersecurity evaluation and software bill of materials was provided.

Human Factors Validation

A human factors and usability engineering process was performed on 780G Insulin Pump with compatible Medtronic CGMs and compatible Medtronic iAGCs 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 780G Insulin Pump's device labeling for users and healthcare practitioners is sufficient and satisfies applicable requirements of 21 CFR 801.

Other Supportive Test Data:

The following additional testing was conducted:

Product Verification (Functional)
Electromagnetic Compatibility (EMC) & RF Wireless Communication
Software Verification

The MiniMed 780G Insulin pump and accessories were subjected to the above tests. All tests passed and met the acceptance criteria. The test results demonstrate that the device met the specified requirements.

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 the 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 outweighs the residual risk, and the overall residual risk is acceptable.

Interoperability

Interoperability documentation was provided in accordance with FDA Guidance “*Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (September 2017)*” and the requirements defined by the ACE special controls 21 CFR 880.5730(b)(3)-(5). It outlined the interoperability strategy and approach for the 780G ACE Pump and how it is interoperable with compatible iAGCs, compatible iCGMs, and compatible interoperable Medtronic CGMs. It also specified expectations, requirements, and interface specifications for current and future interoperable devices. In addition, it outlined Medtronic’s approach to working with connected device companies.

Pre-determined Change Control Plan (PCCP)

Refer to **K251032**.

Conclusion

Based on the information provided in this Traditional 510k, Medtronic concludes that the subject device, MiniMed 780G Insulin Pump, is substantially equivalent to the predicate device, MiniMed 780G Insulin Pump (**K251032**) for the Product Code QFG. Additionally, Medtronic concludes the bolus calculator within the 780G Insulin Pump is substantially equivalent to the predicate device, the Medtronic InPen Dose Calculator (**K242775**) for the Product Code NDC. Furthermore, the subject device meets all the Special Controls requirements for Alternate controller enabled infusion pump defined in 21 CFR 880.5730.