July 1, 2025

Medtronic MiniMed Inc.
Hemang Kotecha
Senior Principal Regulatory Affairs Specialist
18000 Devonshire Street
Northridge, California 91325

Re: K251032
Trade/Device Name: MiniMed 780G insulin pump
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: April 3, 2025
Received: April 3, 2025

Dear Hemang Kotecha:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy

source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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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)*
K251032

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 pumpis 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.

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

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510(K) Summary
K251032

510(k) Submitter Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Hemang Kotecha Senior Principal Regulatory Affairs Specialist +1 857-203-1151 hemang.kotecha@medtronic.com
Secondary Contact Person	Carli Smith Senior Regulatory Affairs Specialist +1 805-558-2408 carli.smith@medtronic.com
Date Prepared	June 23, 2025

Device Information

Device Trade Name	MiniMed 780G insulin pump
Device Common Name	Alternate Controller Enabled Infusion Pump (ACE Pump)
Device Classification Name	Alternate Controller Enabled (ACE) 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	Tandem t:slim X2 Insulin Pump with Interoperable Technology (K232380)
NDC	InPen Dose Calculator (K242775)

Device Description

The MiniMed 780G insulin 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 MiniMed 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 MiniMed 780G insulin pump is an interoperable device that can communicate via a *Bluetooth Low Energy (BLE) wireless electronic interface* with digitally connected devices. The MiniMed 780G insulin 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 MiniMed 780G insulin 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 individuals 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 **Tandem t:slim X2 insulin pump with interoperable technology** **(K232380)**	**Subject Device** **MiniMed 780G insulin pump**
Manufacturer	Tandem Diabetes Care, Inc.	Medtronic MiniMed Inc.
Device Trade Name	Tandem t:slim X2 insulin pump with interoperable technology	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 Tandem t:slim X2 insulin pump with interoperable technology (K232380)	Subject Device MiniMed 780G insulin pump
Indications for Use/Intended Use	The t:slim X2 Insulin Pump with Interoperable Technology (the 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 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 Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.	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 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.
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	2 years and older	7 years and older
Glucose Target (Target Range Settings)	The Tandem t:slim X2 insulin pump targets the following glucose range: 112.5 – 160 mg/dL (6.2 – 8.9 mml/L)	The MiniMed 780G insulin 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)
Technological Characteristics	The t:slim X2 insulin pump with interoperable technology is an ambulatory, battery operated, rate-programmable 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 includes a disposable cartridge which is motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.	The MiniMed 780G insulin 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.
Intended Population	Persons with diabetes mellitus ages 2 and up	Persons with diabetes mellitus ages 7 and up
Specific Drug/Biological Use	U-100 insulin: Novolog® Humalog®	U-100 insulin: Novolog® Humalog® Admelog®

	Predicate Device **Tandem t:slim X2 insulin pump with interoperable technology** **(K232380)**	**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 – 15 U/hour	0 – 35 U/hour
Insulin Delivery Profiles (Basal and Bolus)	6	8
Insulin Bolus Delivery Range	Minimum bolus: 0.05 units Maximum bolus: 25 units	Minimum bolus: 0.025 units Maximum bolus: 25 units
Bolus Increments (Bolus Resolution)	0.01 units	0.025 units
Basal Delivery Accuracy (per 60601-2-24)	±5%	**SAME** Intermediate basal delivery (1 UPH) must meet ±5% of expected
Bolus Delivery Accuracy (per 60601-2-24)	±5%	**SAME** Delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.
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	Compatible FDA cleared infusion sets 3mL sterile syringe 26 gauge needle AC power supply DC car adaptor power supply with USB Tandem Device Updater Alternate USB Cable	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)

	Predicate Device **Tandem t:slim X2 insulin pump with interoperable technology** **(K232380)**	**Subject Device** **MiniMed 780G insulin pump**
Compatible Interoperable Devices	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Automated Glycemic Controllers (iAGCs)	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Automated Glycemic Controllers (iAGCs) 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	Commercially available BG meters that meet ISO 15197:2013
Alarm Type(s)	Visible, audible, vibratory	**SAME**
Pump Notifications, Alerts, Alarms, and Reminders Visible to User	The following are visible on the pump: • Reminders • Alerts • Alarms • Notifications	**SAME**
Logging Records of Critical Events	Critical events logged by the system include: • A record of all drug delivery • Commands issued to the pump and pump confirmations • Device malfunctions • Alarms and alerts and associated acknowledgements • Connectivity events (e.g., establishment or loss of communications) • Bolus requests and terminations (canceling and stopping a bolus) from the t:connect mobile app	Critical events logged by the system include: • 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)
Battery Type/ Power Requirements	The pump uses a re-chargeable lithium-polymer battery	The pump requires one AA (1.5V) battery
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 140°F (60°C) Humidity: 20% to 90% R relative humidity	Temperature: -4°F (-20°C) to 122°F (50°C) Humidity: 20% to 90% R relative humidity
Moisture Protection	IPX7: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes	IPX8: Protected against immersion in water up to 8 feet (2.4 meters) for up to 30 minutes
Pump Screen/Controls	Liquid Crystal Display (LCD) touchscreen	Liquid Crystal Display (LCD) Screen + Keypad

	Predicate Device Tandem t:slim X2 insulin pump with interoperable technology (K232380)	Subject Device MiniMed 780G insulin pump
Wireless control of bolus insulin therapy	The t:connect mobile app can allow limited, wireless control of bolus insulin therapy	The MiniMed 780G insulin pump does not have the capability to wirelessly control bolus insulin delivery via a mobile app.

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	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. The device is indicated for use with Fiasp, NovoLog®, or Humalog® U-100 insulin. 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.	The MiniMed 780G insulin 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®
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

Delivery volume accuracy (DVA) testing for the MiniMed 780G insulin pump was conducted to assess the delivery volume accuracy performance of the pump for foreseeable use conditions as required by the ACE special controls requirements stated in 21 CFR 880.5730(b). The test results support that the device is safe to use under foreseeable use conditions and expected environments.

The following accuracy data for basal delivery, bolus delivery, and occlusion detection were collected and evaluated by Medtronic and confirmed to be acceptable.

To assess basal and bolus delivery accuracy and occlusion detection, 32 MiniMed 780G insulin pumps were tested by delivering at minimum, intermediate, and max basal rates (0.025, 1.0, and 35 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with new infusion sets and reservoirs, and eight with infusion sets and reservoirs which underwent real time aging. Humalog placebo was used as a substitute for insulin for this testing. The Humalog placebo was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Basal Delivery:

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and max basal rate settings for all pumps tested.

Minimum Basal Rate Delivery Performance (0.025 U/hr)

Basal Duration (Number of Units Delivered with 0.025 U/hr Setting)	1 hour (0.025 U)	6 hours (0.15 U)	12 hours (0.3 U)
Amount Delivered [min, max]	0.041 U [0.000 U, 0.094 U]	0.219 U [0.052 U, 0.364 U]	0.518 U [0.171 U, 0.695 U]

Intermediate Basal Rate Delivery Performance (1.0 U/hr)

Basal Duration (Number of Units Delivered with 1.0 U/hr Setting)	1 hour (1U)	6 hours (6 U)	12 hours (12 U)
Amount Delivered [min, max]	0.89 U [0.81 U, 0.98 U]	5.81 U [5.62 U, 6.03 U]	11.79 U [11.46 U, 12.11 U]

Maximum Basal Rate Delivery Performance (35.0 U/hr)

Basal Duration (Number of Units Delivered with 35.0 U/hr Setting)	1 hour (35 U)	6 hours (210 U)
Amount Delivered [min, max]	33.21 U [31.53 U, 34.39 U]	205.33 U [203.31 U, 206.18 U]

Bolus Delivery:

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes.

The table below shows average, minimum, and maximum bolus sizes observed.

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	**Target Bolus Size (U)**	**Mean Bolus Size (U)**	**Min Bolus Size (U)**	**Max Bolus Size (U)**
Min Bolus Delivery Performance (n=800 boluses)	0.025	0.024	0.004	0.041
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.45	2.23	2.57
Max Bolus Delivery Performance (n=320 boluses)	25.00	24.58	22.43	25.91

The following tables below show the number of boluses which were observed to be within the specified range for min bolus, intermediate bolus, and max bolus, respectively.

Min Bolus Delivery Performance (0.025U) (n=800 boluses)

Units of Insulin Delivered After a 0.025 U Bolus Request										
	<0.006 (<25%)	**0.006–0.019 (25–75%)**	**0.019–0.023 (75–90%)**	**0.023–0.024 (90–95%)**	**0.024–0.026 (95–105%)**	**0.026–0.028 (105–110%)**	**0.028–0.031 (110–125%)**	**0.031 –0.044 (125–175%)**	**0.044–0.063 (175–250%)**	**>0.063 (>250%)**
Number and Percent of Boluses within Range	2/800	116/800	179/800	72/800	133/800	111/800	106/800	81/800	0/800	0/800
	(0.3%)	(14.5%)	(22.4%)	(9.0%)	(16.6%)	(13.9%)	(13.3%)	(10.1%)	(0.0%)	(0.0%)

Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)

Units of Insulin Delivered After a 2.5 U Bolus Request										
	<0.625 (<25%)	**0.625–1.875 (25–75%)**	**1.875–2.25 (75–90%)**	**2.25–2.375 (90–95%)**	**2.375–2.625 (95–105%)**	**2.625–2.75 (105–110%)**	**2.75–3.125 (110–125%)**	**3.125–4.375 (125–175%)**	**4.375–6.25 (175–250%)**	**>6.25 (>250%)**
Number and Percent of Boluses within Range	0/800	0/800	1/800	25/800	774/800	0/800	0/800	0/800	0/800	0/800
	(0.0%)	(0.0%)	(0.1%)	(3.1%)	(96.8%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Max Bolus Delivery Performance (25U) (n=320 boluses)

Units of Insulin Delivered After a 25 U Bolus Request										
	<6.25 (<25%)	**6.25–18.75 (25–75%)**	**18.75–22.5 (75–90%)**	**22.5–23.75 (90–95%)**	**23.75–26.25 (95–105%)**	**26.25–27.5 (105–110%)**	**27.5– 31.25 (110–125%)**	**31.25–43.75 (125–175%)**	**43.75–62.5 (175–250%)**	**>62.5 (>250%)**
Number and Percent of Boluses within Range	0/320	0/320	0/320	0/320	320/320	0/320	0/320	0/320	0/320	0/320
	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(100.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Occlusion Detection:

To assess occlusion detection activity, the pumps were tested by placing a hemostat clamp on the cannula of an infusion site (to simulate an occlusion) and then delivering either a 10-unit bolus tested at two different bolus speeds (Standard and Quick) or at three different basal rates denoted as "minimum", "intermediate", and "maximum". Upon start of each test leg, the time elapsed between start of delivery and when the occlusion alarm occurred via the MiniMed 780G insulin pump was recorded. All samples tested met performance that is presented in the table below.

Bolus Duration for Standard and Quick Speeds

Characteristic	Value
Bolus – Standard Speed	1.5 units/min
Bolus – Quick Speed	15 units/min

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (Standard Speed – 10 units)	1 minute, 42 seconds	2 minutes, 24 seconds
Bolus (Quick Speed – 10 units)	10 seconds	16 seconds
Basal (1 units/hr)	2 hours, 58 minutes	4 hours, 3 minutes
Basal (35 units/hr)	2 minutes, 30 seconds	4 minutes
Basal (0.025 units/hr)	174 hours, 53 minutes	199 hours

**The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.*

Catheter Occlusion Detection

Catheter Occlusion Detection testing for the MiniMed 780G insulin pump was conducted with Humalog, NovoLog, and Admelog U100 insulins 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.

Drug Stability and Compatibility

Drug stability and compatibility testing was performed with U100 insulins (Humalog, NovoLog, Admelog) used with the MiniMed 780G insulin pump. The test results demonstrated that the MiniMed 780G insulin pump does not adversely affect the insulins being delivered, and that the insulin types do not adversely affect the pump.

Data Logging

The MiniMed 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 MiniMed 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 MiniMed 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 MiniMed 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 MiniMed 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 (Hardware and Functional)	Electrical, Mechanical and Thermal (EMT) Safety
Biocompatibility	Electromagnetic Compatibility (EMC) & RF Wireless Communication
Reliability	Software Verification
Shelf Life	Packaging and Shipping
Reprocessing (Cleaning instructions)	

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 MiniMed 780G insulin 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.

Predetermined Change Control Plan (PCCP)

A Predetermined change control plan (PCCP) for planned modifications to the MiniMed 780G insulin pump, was provided in accordance with the FDA *Draft* Guidance, *"Predetermined Change Control Plans for Medical Devices (August 2024)".* It included modifications for integrating with potential additional commercialized interoperable devices in the future. The PCCP included a description of modifications, a modification protocol, traceability from modifications to the modification protocols and an impact assessment.

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, Tandem t:slim X2 insulin pump with interoperable technology (K232380) for the Product Code QFG. Additionally, Medtronic concludes the bolus calculator within the MiniMed 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.