# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K251032

### B Applicant

Medtronic MiniMed Inc.

### C Proprietary and Established Names

MiniMed 780G insulin pump

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| QFG | Class II | 21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump | CH - Clinical Chemistry |
| NDC | Class II | 21 CFR 868.1890 - Predictive pulmonary-function value calculator | CH - Clinical Chemistry |

### A Purpose of Submission

- Clearance of the MiniMed 780G insulin pump as an alternate controller enabled (ACE) insulin pump device.
- Establish a Pre-Determined Change Control Plan (PCCP) for integration with other FDA-cleared iCGMs that have demonstrated compatibility with the iAGC embedded in the MiniMed 780G insulin pump.

## II Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for 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.

**C Special Conditions for Use Statement(s):**
Rx - For Prescription Use Only

- Do not use the MiniMed 780G insulin pump or additional system devices next to other electrical equipment, which may cause interference. This includes mobile communication devices such as cell phones that are not paired with the MiniMed 780G system, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1 W. The recommended separation distance between the insulin pump and common RF emitters is 12 in (30 cm).
- Special Precautions regarding Electromagnetic Compatibility (EMC): This body-worn device is intended to be operated within a residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist. Technologies that emit these fields include: cellular phones that are not paired with the MiniMed 780G system, wireless technology, electric can openers, microwaves, and induction ovens. The MiniMed 780G system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
- Do not expose the pump or sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). Strong magnetic fields can cause the system to malfunction, and result in serious injury. If the pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of the system which may lead to health risks such as hypoglycemia or hyperglycemia.
- Remove the pump and sensor before entering a room with x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make the devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over-delivery and severe hypoglycemia.
- Do not expose the pump to a magnet, such as pump cases that have a magnetic clasp. Exposure to a magnet may interfere with the motor inside the pump. Damage to the motor can cause the device to malfunction, and result in serious injury.
- Do not send the pump or sensor through an x-ray scanning machine. The radiation can damage the pump components that regulate insulin delivery, and may result in over-delivery of insulin and hypoglycemia. All system components, including the pump and sensor, must be removed prior to being screened with a full-body scanner. To avoid system removal, request an alternative screening method, if necessary.
- Always monitor your blood glucose (BG) during air travel. Changes in air pressure that occur during flight takeoff and landing can cause over-delivery or under-delivery of insulin, which

may result in hypoglycemia or hyperglycemia. Be ready to respond to alerts and symptoms. Talk with your healthcare professional to see if you need a different treatment plan in place.
- Do not wear or place your pump more than 14 in (35.5 cm) above your infusion site. Doing so can cause an over-delivery of insulin, which may result in hypoglycemia.

## III Device/System Characteristics:

The device is the MiniMed 780G insulin pump that 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.

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 set to an individual's needs. The user interface and alerts provide the user with the ability to interact with the pump delivery system and iAGC.

## IV Substantial Equivalence Information:

### A Predicate Device Name(s):
t:slim X2 Insulin Pump with Interoperable Technology
InPen System App (MMT-8060 (iOS), MMT-8061 (Android))

### B Predicate 510(k) Number(s):
K232380
K242775

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | K251032 | K232380 |
|---|---|---|
| Trade name | MiniMed 780G insulin pump | t:slim X2 insulin pump with interoperable technology |
| **General Device Characteristics** | | |
| Intended Use / Indications for Use | The device is intended for the subcutaneous delivery of insulin, at set and variable rates, for the | Same |

| | | |
|---|---|---|
| | management of diabetes mellitus in persons requiring insulin. The device 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 device is intended for single patient use and requires a prescription. | |
| Intended use population | 7 years and older | 2 years and older |
| Environment of Use | Professional healthcare facilities and home environments | Same |
| | | |
| Insulin Type | U-100 insulin: Novolog, Humalog, and Admelog | U-100 insulin: Novolog and Humalog |
| Operating Modes | Manual Mode and Auto Mode | Same |
| Insulin Delivery Modes | Basal and bolus | Same |
| Basal Flowrates | 0 – 35 U/hr | 0 – 15 U/hr |
| Basal Delivery Accuracy | ±5% for 1 U/hr and up | ±5% |
| Bolus Range and increment | 0.025 U to 25 U, 0.025 U increment | 0.05 U to 25 U, 0.01 U increment |
| Bolus Delivery Accuracy | ±5% for bolus volumes ≥ 0.1 U | ±5% |
| Bolus Canceling | Supports bolus cancellation | Same |
| | | |
| Alarms | Visible, audible, vibratory | Same |
| Pump Notifications, Alerts, Alarms, and Reminders Visible to User | The following are visible on the pump:<br>• Reminders<br>• Alerts<br>• Alarms<br>• Notifications | Same |
| Pump Screen/Controls | Liquid Crystal Display (LCD) Screen + Keypad | Liquid Crystal Display (LCD) touchscreen |
| Connectivity | Bluetooth Low Energy (BLE) | Same |
| Ingress Protection | IPX8 | IPX7 |

| **Device & Predicate Device(s):** | K251032 | K242775 |
|---|---|---|
| Trade name | MiniMed 780G insulin pump | InPen Dose Calculator |
| **General Device Characteristics** | | |
| Intended Use / Indications for Use | The device calculates an insulin dose based on user-entered data. | The device calculates an insulin dose or carbohydrate intake based on user entered data. |
| Prescription Use | Prescription is required | Same |
| Therapy Type | Insulin pump therapy | Multiple daily insulin injection therapy |
| Intended use population | 7 years and older | 2 years and older |
| Environment of Use | Professional healthcare facilities and home environments | Home use |
| | | |
| Insulin Type | U-100 insulin: Novolog, Humalog, and Admelog | U-100 insulin: Fiasp, Novolog, and Humalog |
| Principles of Operation | Calculate insulin doses for meals and corrections while accounting for active insulin (insulin on board). | Same |
| Carbohydrate estimate | Based on user-entered data | Based on either user-entered carbohydrate, meal size estimation, or fixed meal doses |
| Requires BG for bolus dose calculation | Yes | Same |
| Manual data entry | Yes | Same |

## V Standards/Guidance Documents Referenced:

- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

## VI Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Basal Delivery Accuracy

To assess basal delivery accuracy, 16 new and 16 aged pumps for a total of 32 unique pumps were tested for each basal rate by delivering insulin at low, medium, and high basal rates (0.025, 1.00, and 35.0 U/hr). The 16 aged pumps were pre-conditioned with simulated shipping and handling, with stressors for simulated 4-year service life, and with real-time shelf-life aging for 10 months.

U-100 Humalog was used for testing. The insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess basal delivery accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warmup period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

**Table 1:** Amount of fluid delivered after 1, 6, and 12 hours with 0.025 U/hr (low) basal rate setting

| **0.025 U/hr Basal Duration** | **1 hour** | **6 hours** | **12 hours** |
|---|---|---|---|
| **Total expected delivery volume** | **0.025 U** | **0.1 U** | **0.3 U** |
| **Median amount delivered** | 0.041 U | 0.219 U | 0.518 U |
| **[min, max]** | [0, 0.094] | [0.052, 0.364] | [0.171, 0.695] |

**Table 2:** Amount of fluid delivered after 1, 6, and 12 hours with 1 U/hr (medium) basal rate setting

| **1 U/hr Basal Duration** | **1 hour** | **6 hours** | **12 hours** |
|---|---|---|---|
| **Total expected delivery volume** | **1 U** | **6 U** | **12 U** |
| **Median amount delivered** | 0.89 U | 5.81U | 11.79 U |
| **[min, max]** | [0.81, 0.98] | [5.62, 6.03] | [11.46, 12.11] |

**Table 3:** Amount of fluid delivered after 1 and 6 hours with 35 U/hr (high) basal rate setting

| **35 U/hr Basal Duration** | **1 hour** | **6 hours** |
|---|---|---|
| **Total expected delivery volume** | **35 U** | **210 U** |
| **Median amount delivered** | 33.21 U | 205.33 U |
| **[min, max]** | [31.53, 34.39] | [203.31, 206.18] |

Note: A measurement at the 12-hour period with 35.0 U/hr basal rate is not applicable to the MiniMed 780G insulin pump as the reservoir will empty prior to this time point.

2. Bolus Delivery Accuracy

To assess bolus delivery accuracy, 16 new and 16 aged pumps for a total of 32 unique pumps were tested for each bolus size by delivering minimum, intermediate, and maximum bolus amounts (0.025, 2.5, and 35 Units). The 16 aged pumps were pre-conditioned with simulated shipping and handling, with stressors for simulated 4-year service life, and with real-time shelf-life aging for 10 months.

U-100 Humalog was used for testing. The insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess bolus delivery accuracy. The number of total and consecutive boluses delivered in this testing for each delivery volume is described in Table 4 below:

**Table 4:** Summary of bolus testing protocol

| **Bolus size (units)** | **Number of pumps tested** | **Consecutive boluses per pump** | **Total boluses** |
|---|---|---|---|
| 0.025 units | 32 | 25 | 800 |
| 2.5 units | 32 | 25 | 800 |
| 25 units | 32 | 10 | 320 |

The actual bolus volume delivered was compared to the expected bolus volume for minimum, intermediate, and maximum boluses. Tables 5-7 below show the number (and %) of boluses within the specified range of each target bolus volume.

**Table 5:** Amount of fluid delivered after a 0.025 U bolus request

| **Units delivered after a 0.025 U bolus request (% of commanded units)** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | <25% | 25-75% | 75-90% | 90-95% | 95-105% | 105-110% | 110-125% | 125-175% | 175-250% | >250% |
| **Number and percent of boluses** | 2/ 800 (0.3%) | 116/ 800 (14.5%) | 179/ 800 (22.4%) | 72/ 800 (9.0%) | 133/ 800 (16.6%) | 111/ 800 (13.9%) | 106/ 800 (13.3%) | 81/ 800 (10.1%) | 0/ 800 - | 0/ 800 - |

**Table 6:** Amount of fluid delivered after a 2.5 U bolus request

| **Units delivered after a 5.0 U bolus request (% of commanded units)** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | <25% | 25-75% | 75-90% | 90-95% | 95-105% | 105-110% | 110-125% | 125-175% | 175-250% | >250% |
| **Number and percent of boluses** | 0/800 - | 0/800 - | 1/800 (0.1%) | 25/800 (3.1%) | 774/800 (96.8%) | 0/800 - | 0/800 - | 0/800 - | 0/800 - | 0/800 - |

**Table 7:** Amount of fluid delivered after a 25 U bolus request

| Units delivered after a 25 U bolus request (% of commanded units) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | <25% | 25-75% | 75-90% | 90-95% | 95-105% | 105-110% | 110-125% | 125-175% | 175-250% | >250% |
| **Number and percent of boluses** | 0/320 - | 0/320 - | 0/320 - | 0/320 - | 320/320 (100%) | 0/320 - | 0/320 - | 0/320 - | 0/320 - | 0/320 - |

3. Occlusion Detection

Occlusion detection testing was conducted using 32 pumps and 5 delivery profiles: 10 U Bolus (Standard Speed – 1.5U/min), 10 U Bolus (Quick Speed – 15U/min), 0.025 U/hr basal, 1 U/hr Basal, and 35 U/hr basal. Each pump was tested for the time between occlusion and pump alarm sequentially and for the 5 delivery profiles. To test the time between occlusion and pump alarm, each pump was physically occluded by clamping the cannula, and a 10 U Bolus (Standard Speed – 1.5U/min), a 10 U Bolus (Quick Speed – 15U/min), a 0.025 U/hr basal, a 1 U/hr Basal, or a 35 U/hr basal were initiated. The time elapsed and the units delivered until an occlusion alarm occurred were recorded. The typical time to occlusion detection in the table below is the average for the samples measured and the maximum time is the absolute maximum. Results are presented in the table below.

**Table 8:** Occlusion detection testing

| | **Typical time to occlusion detection** | **Maximum time to occlusion detection** |
|---|---|---|
| **10 U Bolus (Standard Speed – 1.5U/min)** | 102 seconds | 144 seconds |
| **10 U Bolus (Quick Speed – 15U/min)** | 10 seconds | 16 seconds |
| **0.025 U/hr basal** | 174 hours and 53 minutes | 199 hours |
| **1 U/hr Basal** | 2 hours and 58 minutes | 4 hours and 3 minutes |
| **35 U/hr basal** | 2.5 minutes | 4 minutes |

The insulin delivered until an occlusion alarm occurred was within the acceptance criteria of 5U.

## B Other Supportive Instrument Performance Characteristics Data:

1. Additional Bench Testing

In addition to the performance testing described above, other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified.

- Delivery accuracy was tested with 4 head height conditions using 16 new and 16 aged pumps for a total of 32 unique pumps.
- Delivery accuracy was tested with 5 unique pumps after exposure to drop, shock, and vibration.
- Delivery accuracy was tested under 6 static and dynamic environmental profiles with 16 new and 16 aged pumps for a total of 32 unique pumps. The sponsor observed large variation in insulin delivery during simulated airplane takeoff and landing, and concluded from their CAPA investigation that outgassing from the insulin product is the root cause of unintended delivery of insulin during flight. Therefore, the sponsor has included the following warning in the labeling: "*Always monitor your blood glucose (BG) during air travel. Changes in air pressure that occur during flight takeoff and landing can cause over-delivery or under-delivery of insulin, which may result in hypoglycemia or hyperglycemia. Be ready to respond to alerts and symptoms. Talk with your healthcare professional to see if you need a different treatment plan in place.*"

2. Interoperability

A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

3. Leveraged Information

The candidate device under this 510(k) submission is identical to the MiniMed 780G pump recently approved as a component of the MiniMed 780G system under P160017/S118, with the exception of the updated intended use which includes interoperability, and the PCCP described below. There have been no design changes to the pump hardware, firmware, principle of operation, or operating modes. Therefore, the following was leveraged from previous submissions: Human Factors, Biocompatibility, Sterility, Insulin Compatibility and Stability, Electromagnetic Compatibility and Wireless Coexistence, Electrical Safety, Data Logging, Software, and Cybersecurity.

4. PCCP

The PCCP specifies the protocols and acceptance criteria for validating integration of additional CGMs in a controlled manner such that the device is as safe and effective as the predicate. The sponsor's PCCP for integration with FDA-cleared iCGMs comprises the following:

- The candidate iCGM must have demonstrated compatibility with the iAGC embedded in the MiniMed 780G insulin pump before the integration.
- Once a compatible candidate iCGM is identified, the modifications made to the device to support integration of the iCGM will be evaluated within the existing risk management framework of the device and be implemented in accordance with Medtronic's QMS procedures. The integration protocol includes methods and processes for developing, verifying, validating, and implementing modifications to the MiniMed 780G insulin pump described under this PCCP.
- The proposed modifications in this PCCP are limited to the Main Application software component of the pump. There are no hardware-related changes in this PCCP. The modifications to the Main Application are intended to ensure that the glucose signals from the candidate iCGM will be processed into suitable format for the iAGC and critical alarms/alerts related to the candidate iCGM will be handled correctly.
- If the integrated system with the candidate iCGM meets the acceptance criteria, the design change will be implemented according to the quality management system and the new iCGM may be added as an interoperable component to the MiniMed 780G insulin pump without additional premarket review. All related labeling including third-party iCGM labeling will be revised to identify the new iCGM according to the quality management system. A communication will be provided through email and the Medtronic webpage to notify users when a new software version has been deployed and is available for upgrade. Post-market surveillance will be collected and analyzed with the third-party iCGM manufacturer.

## 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.