



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K253470

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 – Calculator, Drug Dose	CH - Clinical Chemistry

E Purpose for Submission:

This submission includes the following changes:

- Addition of compatible U-100 insulins Fiasp® and Lyumjev® for use with the MiniMed 780G insulin pump

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.

II Device Description

The MiniMed 780G Insulin Pump is an alternate controller enabled (ACE) insulin pump intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The pump can reliably and securely communicate with compatible, digitally connected medical devices, including interoperable continuous glucose monitors (iCGMs) and interoperable automated glycemic controllers (iAGCs). The pump is intended to be used both alone and in conjunction with compatible digitally connected medical devices for the purpose of insulin 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 a single physical device. The pump includes a bolus calculator that calculates insulin doses based on user-entered data.

The pump provides the user with keypad controls and a display screen for configuring therapy settings and viewing real-time glucose information, glucose trends, alerts, alarms, and other therapy-related information. The user interface and alerting system enable user interaction with the pump delivery system and interoperable automated glycemic control functionality when used with compatible devices.

Product code NDC applies solely to the embedded bolus calculator function and does not constitute a drug evaluation or combination-product review.

III Substantial Equivalence Information:

A Predicate Device Name(s):

MiniMed 780G Insulin Pump
Medtronic InPen dose calculator

B Predicate 510(k) Number(s):

K251032
K242775

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K253470</u>	<u>K251032</u>
Device Trade Name	MiniMed 780G insulin pump	MiniMed 780G insulin pump
General Device Characteristic	<u>K253470</u>	<u>K251032</u>

Similarities		
Intended Use/Indications For Use	The device is intended for the subcutaneous delivery of insulin, at set and variable rates, for the 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.	Same
General Device Characteristic Differences	<u>K253470</u>	<u>K251032</u>
Compatible Insulins	U-100 insulin (e.g., Humalog®, NovoLog®, Admelog®, Fiasp®, Lyumjev®)	U-100 insulin (e.g., Humalog®, NovoLog®, Admelog®)
Software	Pump software version 6.61, implemented under the PCCP authorized in K251032 to enable pump-side interoperability with compatible interoperable CGMs, along with related configuration and user-interface updates	Pump software version 6.42
Cybersecurity	Cybersecurity controls consistent with the predicate device; updates implemented under the PCCP authorized in K251032 to support pump-side interoperability and routine cybersecurity maintenance	Cybersecurity controls consistent with ACE pump special controls
Device & Predicate Device(s):	K253470	K242775

Device Trade Name	MiniMed 780G insulin pump	InPen Dose Calculator
General Device Characteristic Similarities	K253470	K242775
Intended Use / Indications for Use	The device calculates an insulin dose based on user-entered data.	Same
Prescription Use	Prescription is required	Same
Principles of Operation	Calculate insulin doses for meals and corrections while accounting for active insulin (insulin on board).	Same
Requires BG for bolus dose calculation	Yes	Same
Manual data entry	Yes	Same
Intended use population	7 years and older	Same
General Device Characteristic Differences	K253470	K242775
Compatible Insulins	U-100 insulin (e.g., Humalog®, NovoLog®, Admelog®, Fiasp®, Lyumjev®)	U-100 insulin: NovoLog® Humalog® Fiasp®
Therapy Type	Insulin pump therapy	Multiple daily insulin injection therapy
Carbohydrate estimate	Based on user-entered data	Based on either user-entered carbohydrate, meal size estimation, or fixed meal doses
Environment of Use	Professional healthcare facilities and home environments	Home use
Therapy Type	Insulin pump therapy	Multiple daily injection (MDI) insulin therapy

IV 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*

V Performance Characteristics:

A. Non-Clinical Performance

The MiniMed 780G insulin pump in this submission is identical in hardware design, pumping mechanism, and essential performance characteristics to the device cleared under K251032. There are no changes to insulin delivery accuracy, reliability, biocompatibility, shelf life, or essential performance.

Accordingly, the following non-clinical performance data were leveraged from K251032 and remain applicable:

- Delivery Volume Accuracy (DVA) testing (basal and bolus)
- Mechanical and functional performance testing
- Reliability and expected service life testing
- Electrical safety and EMC testing
- Wireless and RF performance testing
- Biocompatibility of patient-contacting materials
- Shelf-life and packaging validation

New non-clinical testing in this submission is limited to drug compatibility and catheter occlusion testing supporting the addition of Fiasp® and Lyumjev®, leveraging previously reviewed data from P160017/S125.

B. Clinical Studies:

Clinical studies evaluating the performance of the MiniMed 780G system with Fiasp® and Lyumjev® were previously reviewed under P160017/S125 and are leveraged for this submission.

C. Other Supportive Device Performance Characteristics Data

Human factors and cybersecurity controls remain consistent with those previously reviewed and accepted under K251032, and software updates implemented under the PCCP do not introduce new use-related or cybersecurity risks affecting safety or essential performance.

VI Proposed Labeling:

The labeling, updated to reflect the addition of compatible insulins, supports the finding of substantial equivalence for this device.

VII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.