510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253743

B Applicant

Medtronic MiniMed, Inc.

C Proprietary and Established Names

MiniMed Flex 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

E Purpose for Submission:

The purpose of this submission is a) clearance for a new device, MiniMed Flex pump, as an alternate controller enabled (ACE) infusion insulin pump device and to b) establish a predetermined change control plan for integration of new, compatible integrated continuous glucose monitors (iCGMs).

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The MiniMed Flex 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 Flex 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 Flex pump is indicated for use in persons 7 years of age and older.

The MiniMed Flex pump is intended for single patient use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

- Always monitor your glucose 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 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, sensor, and the App Manager or mobile device 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.

III Device Description

The MiniMed Flex 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 in conjunction with compatible, digitally connected medical devices for the purpose of drug delivery.

The MiniMed Flex pump is an ambulatory, battery-operated, rate-programmable micro-infusion pump. It is a screenless, tubed pump that houses electronics, a pumping mechanism, and a medication reservoir within the same physical device. It is intended for use with compatible

insulin reservoir and insulin infusion set for delivery of basal and bolus insulin according to settings selected or inputs entered by the user or compatible iAGC software based on healthcare provider recommendations.

The primary user interface and primary display for the MiniMed Flex pump is the MiniMed app, also the user interface for the compatible MiniMed iAGCs, which runs on a compatible iOS or Android device.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Minimed 780G insulin pump

B Predicate 510(k) Number(s):

K251032

C Comparison with Predicate(s):

Device & Predicate Device(s):	Subject Device (K253743)	Predicate Device (K251032)
Device Trade Name	MiniMed Flex pump	MiniMed 780G insulin pump
General Device Characteristic 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

Intended use population	Persons with diabetes mellitus ages 7 and up	Persons with diabetes mellitus ages 7 and up
Environment of Use	Home environments	SAME
Insulin Type	The following U-100 insulin products: Novolog® Humalog® Admelog® Lyumjev® Fiasp®	SAME
Operating Modes	Manual mode, SmartGuard Mode	SAME
Insulin Delivery Modes	Basal and Bolus	SAME
Bolus Canceling	Supports bolus cancellation	SAME
Alarms	Visible, audible, auditory	SAME
General Device Characteristic Differences		
Basal Flowrates	0 – 15 U/hour	0 – 35 U/hour
Bolus Range and increment	Minimum bolus: 0.05 units Maximum bolus: 25 units	Minimum bolus: 0.025 units Maximum bolus: 25 units
Pump Notifications, Alerts, Alarms, and Reminders Visible to User	Visible to the user on the pump through sound and lights.	Visible to the user on the pump screen: Reminders, Alerts, Alarms, Notifications
Pump Screen/Controls	Screenless. Users receive safety critical alerts from the pump's lights and speaker. The user has limited interaction with the pump through two buttons (the action button and the acknowledge button) and the	Liquid Crystal Display (LCD) Screen + Keypad

	status light. Alerts are communicated to the MiniMed app where notifications are presented for the user to review and acknowledge.	
Connectivity	Minimed App (installed on compatible smartphone or App manager)	N/A
Ingress Protection	IPX8: Protected against immersion in water up to 8 feet (2.4 meters) for up to 1 hour 45 minutes	IPX8: Protected against immersion in water up to 8 feet (2.4 meters) for up to 30 minutes

In addition to the similarities and differences between the candidate and predicate devices, the candidate device has an authorized Predetermined Change Control Plan (PCCP) to allow for future software modifications that ensure its compatibility and interoperability with new integrated Continuous Glucose Monitors (iCGM). These modifications include updating the electronic interface for sensor pairing, integrating iCGM-specific alerts and status information, adding a sensor data processing module to ensure data from new sensors is in an acceptable format for the pump's embedded therapy algorithms and for expansion of indications for use to users below 7 years of age. See Section VI.C for more information.

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:

A. Non-Clinical 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 (0.05, 1.00, and 15.0 U/hr). The 16 aged pumps were pre-conditioned with simulated 4-year service life, and with real-time shelf-life aging for 6 months.

U-100 Humalog placebo was used for testing. The placebo 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 0.05 U/hr (low) basal rate setting

0.05 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.05 U**	**0.3 U**	**0.6 U**
Median amount delivered	0.063 U	0.329 U	0.670 U
[min, max]	[0.039, 0.093]	[0.239, 0.393]	[0.512, 0.775]

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	0.94 U	5.84 U	11.75 U
[min, max]	[0.86, 0.98]	[5.41, 6.01]	[11.55, 11.99]

Table 3: Amount of fluid delivered after 1, 6 and 12 hours with 15 U/hr (high) basal rate setting

15 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**15 U**	**90 U**	**180 U**
Median amount delivered	14.66 U	88.49 U	177.02 U
[min, max]	[14.38, 14.77]	[88.26, 88.72]	[176.70, 177.43]

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 to simulate six months of shelf life and 4-year service life.

U-100 Humalog placebo was used for testing. The placebo 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
0.05 units	32	25	800
2.5 units	32	25	800
25 units	32	10	320

Table 5: Amount of fluid delivered after a 0.05 U bolus request

Units delivered after a 0.05 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	4/ 800 (0.5%)	36/ 800 (4.5%)	159/ 800 (19.9%)	172/ 800 (21.5%)	194/ 800 (24.3%)	109/ 800 (13.6%)	115/ 800 (14.4%)	11/ 800 (1.4%)	0/ 800 -	0/ 800 -

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

Units delivered after a 2.5 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 -	8/800 (1.0%)	44/800 (5.5%)	742/800 (92.8%)	4/800 (0.5%)	2/800 (0.3%)	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 4 delivery profiles: 25 U Bolus, 0.05 U/hr basal, 1 U/hr Basal, and 15 U/hr basal. Sixteen of the pumps were new, and 16 were aged to simulate 6 months of shelf life and 4 years of regular use. New and aged reservoirs and infusion sets were also used as part of testing. To test the time between occlusion and pump alarm, each pump was physically occluded by clamping the cannula. 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.

Table 8: Occlusion detection testing

	Typical time to occlusion detection	**Maximum time to occlusion detection**
25 U Bolus	33 seconds	47 seconds
0.05 U/hr basal	42 hours and 49 minutes	71 hours, 19 minutes
1 U/hr Basal	1 hours and 52 minutes	2 hours and 41 minutes
15 U/hr basal	7 minutes	9 minutes

At 1 U/hr the maximum post-clearance bolus was 1.61 U.

B. Other Supportive Device Performance Characteristics Data

4. 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 8 new and 8 aged pumps, all with aged consumables after exposure to cyclical stressors of chemicals, drops, cleaning, motor use, infusion set swapping, and button pressing.
   - Delivery accuracy was tested under a total of 6 static and dynamic environmental profiles with 16 new and 16 aged pumps for a total of 32 unique pumps.

5. Software and Cybersecurity
   The software and cybersecurity documentation provided was determined to be adequate to support substantial equivalence.

6. 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.

7. Biocompatibility
   Biocompatibility testing was performed per FDA Guidance Document: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and FDA special controls for alternate controller enabled infusion pump. Results support a determination of substantial equivalence.

8. Sterility
   The Minimed Flex pump is non-sterile. Medtronic has performed adequate cleaning validation to demonstrate substantial equivalence.

9. Human Factors
   Human Factors validation testing assessed users aged 2+ years old diagnosed with either type 1 diabetes or type 2 diabetes with a total of 60 users tested across four distinct user groups and included independent users and dependent users with their caregiver. The users had a mix of insulin pump experience and consisted of users currently on multiple daily injections of insulin, current MiniMed pump users and users who utilize other pumps or automated insulin delivery systems. Training was tailored to specific users' needs and consisted of both virtual training via video and training through a certified trainer that was trained by the manufacturer.

10. Electromagnetic Compatibility and Electrical Safety
    Electromagnetic compatibility and electromagnetic immunity and wireless coexistence testing was performed for the pump. The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. All tests demonstrated that the device would perform as expected in the home healthcare environment.

11. Wireless Coexistence
    Evaluated per ANSI/IEEE C63.27-2021, as well as range and household coexistence protocols. Reports demonstrated robust BLE communication in coexistence, range, and household environments with no loss of safety or performance.

12. Leveraged Information
    The Minimed Flex pump shares the same fluid pathway as that of the predicate device and hence the insulin compatibility was leveraged from predicate device.

13. PCCP
    The PCCP documents how the MiniMed Flex ACE Pump will be modified via software updates to be compatible with integrated Continuous Glucose Monitors (iCGM). It describes the modification protocols, traceability, and impact assessment for these integrations.
    The planned modifications include:
    1. iCGM Integration and Pairing: Updating the pump's electronic interface and communication protocols to support pairing and data exchange with new iCGM sensors.
    2. Pump-side Data Processing: Migrating and implementing several data processing functions from the CGM to the pump firmware and historical data backfilling.
    3. Updated Status and Alert Handling: Integrating iCGM-specific status information, state information, and alerts into the pump's software.

The scope of the modifications is restricted to software changes for iCGM interoperability, and the modifications and their associated testing are provided below:

Specific Modifications	**Performance Evaluation Methods for Verifying and Validating PCCP Modifications**
Updates to the pump's electronic interface for new iCGM sensor information and sensor pairing	• Software Verification • Pump Product Verification • System Verification • EMC and RF Wireless Testing • Cybersecurity Testing • Human Factors Assessment
Integration of iCGM-related status and state information	• Software Verification • Pump Product Verification • System Verification • Human Factors Assessment
Updates to the pump's electronic interface for new iCGM sensor information and sensor pairing.	• Software Verification Testing • Pump Product Verification Testing • System Verification Testing
Addition of a sensor data processing module to ensure iCGM data is in an acceptable format for the glycemic controller algorithm embedded in the pump.	• Software Verification Testing • Pump Product Verification Testing • System Verification Testing
Migration of the specific firmware from the CGM to the pump firmware.	• Software Verification Testing • Pump Product Verification Testing • System Verification Testing
Implementation of sensor backfill data processing to handle data from periods of lost communication.	• Software Verification Testing • Pump Product Verification Testing • System Verification Testing
Expand age indications to include 2- to 6-year-olds	• Human Factors Assessment

For the MiniMed Flex ACE Pump, the method for implementing a modification is as follows:

- Evaluate modifications within the existing risk management framework and implement them in accordance with the quality management system procedures.
- Implement the changes in a future iterative software version.
- Update labeling (Instructions for Use, System Technical Guide) to include iCGM-related information.
- Deploy software updates to the pump via a Firmware-Over-The-Air (FOTA) process.
- Communicate the availability of the software upgrade to users and healthcare providers.
- Conduct post-market surveillance to collect and analyze data on the device's performance.

Finally, the changes implemented via the PCCP need to also follow an impact assessment, as the changes do not impact the intended use of the MiniMed Flex pump, do not introduce new or significantly modified risks, nor raise new questions of safety and effectiveness.

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.