510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K210714

B Applicant

Medtronic MiniMed, Inc.

C Proprietary and Established Names

Extended Reservoir

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZG	Class II	21 CFR 880.5725 – Infusion Pump	Clinical Chemistry

E Purpose for Submission:

Modification of a previously cleared reservoir for extending the duration of use to up to 7 days.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Extended Reservoir is indicated for the subcutaneous infusion of medication, including insulin, from compatible Medtronic insulin pumps and infusion sets. Refer to your Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

The pump reservoir should be used for a maximum of seven days, or according to the insulin labeling, whichever is shorter.

Do not use with two or three day infusion sets. The reservoir may only be used for up to seven days with use of the Medtronic Extended infusion set. Use of the reservoir with two or three day infusion sets may lead to hyperglycemia or diabetic ketoacidosis.

If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.

III Device Description

The Extended Reservoir is a sterile medication container designed for single use. The device is a component of the Medtronic Insulin Pump Delivery System used by patients with diabetes mellitus, requiring subcutaneous administered insulin, to maintain acceptable blood glucose levels. The device is designed to mechanically connect to compatible infusion sets (e.g., Medtronic Extended Wear Infusion Set, K210544). The Medtronic MiniMed Extended Reservoir has a 3.0 mL storage capacity and is indicated for use for up to 7 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Medtronic MiniMed Paradigm Reservoir Model MMT-332A

B Predicate 510(k) Number(s):

K032005

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210714	K032005
Device Trade Name	Extended Reservoir	Medtronic MiniMed Paradigm Reservoir MMT-332A
General Device Characteristic Similarities		
Intended Use	Subcutaneous infusion of medication, including insulin, from	Same

	compatible Medtronic insulin pumps and infusion sets.	
Sterilization Method	Ethylene Oxide	Same
Insulin Compatibility	Humalog (insulin lispro) and Novolog (insulin aspart)	Same
Shelf Life	3 years	Same
Nominal Volume	3 mL	Same
General Device Characteristic Differences		
Duration of Use	Up to 7 days	Up to 3 days

V Standards/Guidance Documents Referenced:

ISO 14971:2019, Medical devices – Application of risk management to medical devices

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

ISO 10993-3:2014, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

ISO 10993-4:2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood

ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for in-vitro Cytotoxicity

ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residual

ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity

ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

ISO 10993-17:2002, Biological Evaluation of Medical Devices – Part 17: Establishment of Allowable Limits for Leachable Substances

ISO 10993-18:2009, Biological Evaluation of Medical Devices – Part 18: Chemical characterization of materials

VI Performance Characteristics:

The sponsor conducted analytical performance tests to evaluate the modified device. The following analytical performance tests were provided:

- Insulin compatibility testing
- Storage and operating conditioning
- Service life testing
- Gravity leak testing
- Occlusion sensitivity

The sponsor also provided the results of biocompatibility testing in accordance with ISO 10993-1 and FDA guidance on the use of this standard. The results of this testing support a finding of substantial equivalence.

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.