July 2, 2024

Medtronic MiniMed
Shruti Prakash
Sr. Regulatory Affairs Specialist
18000 Devonshire St
Northridge, California 91325

Re: K241622
Trade/Device Name: Extended Reservoir; MiniMed Reservoir
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: June 5, 2024
Received: June 5, 2024

Dear Shruti Prakash:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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.

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 Toxicology Devices
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.

Submission Number *(if known)*

Device Name

MiniMed Reservoir
Extended Reservoir

Indications for Use *(Describe)*

MiniMed Reservoir- This 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 compatibility.

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

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.

510(k) Summary

MiniMed Reservoir
Extended Reservoir

Table 1-1: General Information

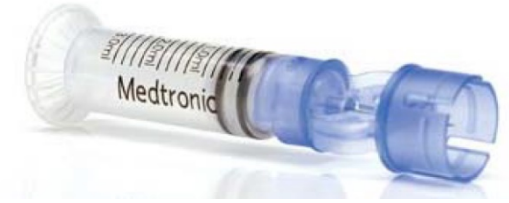
Device Trade/ Generic Name	MiniMed Reservoir Extended Reservoir
Predicate Device Name and Model ID	MiniMed Reservoir 1.8mL (MMT-326A) MiniMed Reservoir 3.0mL (MMT-332A) Extended Reservoir (MMT-342, MMT-342G)
Predicate 510(k) Number	**K001828** **K032005** **K210714**
Classification Name	Class II Infusion Pump Accessory
Pro Code	LZG
Cite	21 CFR 880.5725
Applicant Registration Number	2032227
Manufacturer and Design Facility	Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA
Manufacturing Facility	(Contract Manufacturer) Medtronic Puerto Rico Operations Co. (MPROC) Road 31, KM 24, HM 4 Ceiba Norte Industrial Park Juncos, Puerto Rico 00777
Establishment Number	3004209178
Primary Contact Information	Shruti Prakash Senior Regulatory Affairs Specialist Tel: (213) 372-9753 Email: shruti.prakash2@medtronic.com
Secondary Contact Information	Christina Rowe Senior Regulatory Affairs Manager Tel: (818) 942-4875 Email : christina.rowe@medtronic.com

1. Device Description

The MiniMed family of reservoirs (MMT-326A, MMT-332A, MMT-342, MMT-342G) (herein referred to as “reservoirs” or “subject devices”) are sterile medication containers (**Figure 1-1** and **Figure 1-2**) designed for single use.

Figure 1-1: MMT-326A Reservoir, 1.8 mL, with Transfer Guard

Figure 1-2: MMT-332A and MMT-342 Reservoir, 3.0 mL, with Transfer Guard



The reservoirs are a component of the Medtronic Insulin Pump Delivery System used by patients with diabetes mellitus, requiring the subcutaneous administration of insulin to maintain acceptable blood glucose levels. The reservoirs are indicated for the subcutaneous infusion of medication, including insulin, from compatible Medtronic insulin pumps (i.e., Paradigm pumps and NGP pumps) and infusion sets. Refer to the Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.

1.1. Principles of Operation

The reservoirs have the same principle of operation as the predicate devices (MMT-326A, MMT-332A, MMT-342, MMT-342G) and are designed to mechanically connect to compatible infusion sets. Reservoirs are connected to the infusion set via the tubing connector (H-Cap), which enables insulin infusion from the reservoir through a fluid path into the subcutaneous tissue.

The reservoirs share all attributes of the predicate devices, including the same intended use, same technological characteristics (i.e., hardware design, material, chemical composition, energy source, etc.), same storage capacity (1.8mL or 3.0mL), and have the same principle of operation as the marketed predicate devices (MMT-326A cleared by FDA under **K001828**; MMT-332A cleared by FDA under **K032005**; and MMT-342 and MMT-342G cleared by FDA under **K210714**). The change is limited to the qualification of an alternate sterilization site and optimized sterilization cycle for the reservoirs. The cycle is considered “optimized”

because it reduces sterilization complexity by consolidating the Medtronic EO sterilization cycles and modifying EO concentration and processing time to improve the overall efficiency of the sterilization process.

An exploded view of the reservoirs is shown in **Figure 1-3**. The associated components are provided in **Table 1-2.**

Figure 1-3: Reservoir Overview

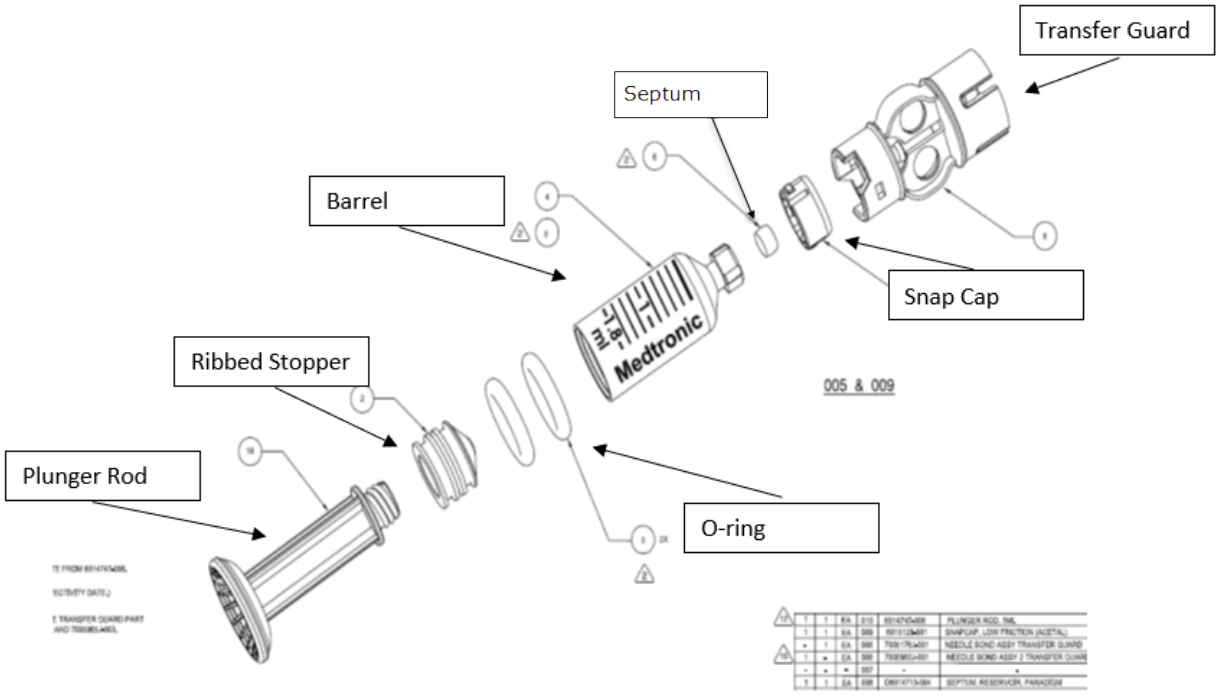


Table 1-2: Reservoir Component/Material Definitions

Component/Material	Definition
Plunger Rod	Rigid handle which can be used to move the stopper for the purposes of filling the reservoir with medication.
Ribbed Stopper	Movable sealing member within the reservoir which is driven by the pump mechanism to deliver medication.
O-Ring	Provides support between the stopper-to-barrel assemblies as it serves as an interface to prevent leaks.
Barrel	A cylindrical plastic container for storing medication.
Septum	Elastomeric, static closure mounted on the Barrel end. The septum is to be penetrated with a needle, and seals around it for filling and infusion.

Component/Material	Definition
Transfer Guard	A plastic component encapsulating a hypodermic needle, designed to facilitate filling of the Reservoir from a vial and to reduce needle-stick probability.
Snap Cap	Connects to the infusion set

2. Indications For Use

2.1. MiniMed Reservoir, 1.8mL (K001828) and 3.0mL (K032005)

This 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 compatibility.

2.2. MiniMed Extended Reservoir (K210714)

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

3. Technological Characteristics and Substantial Equivalence (SE)

The scope of the change is limited to qualifying an additional sterilization site and implementing an optimized sterilization cycle for the reservoirs. The hardware design of the reservoirs is the same as the predicate device. Additionally, there are no changes in the manufacturing, packaging, fluid capacity, insulin compatibility, or reservoir assembly between the predicate and the subject devices.

A substantial equivalence (SE) chart detailing the similarities and differences between the predicate devices and the subject devices is shown in **Table 3-1**.

Table 3-1: Comparison of Predicate Device to Subject Device

Specification	Predicate Devices **MiniMed Reservoir 1.8mL (MMT-326A, K001828)** **MiniMed Reservoir 3.0mL (MMT-332A, K032005)** **Extended Reservoir (MMT-342, MMT-342G, K210714)**	Subject Devices **MiniMed Reservoir 1.8mL (MMT-326A, K001828)** **MiniMed Reservoir 3.0mL (MMT-332A, K032005)** **Extended Reservoir (MMT-342, MMT-342G, K210714)**	Comparison
Type of Device	User-filled reservoir	User-filled reservoir	Same
Intended Use	The MiniMed Reservoir is indicated for the subcutaneous infusion of medication, including insulin, from compatible Medtronic insulin pumps and infusion sets. Refer to the Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.	The MiniMed Reservoir is indicated for the subcutaneous infusion of medication, including insulin, from compatible Medtronic insulin pumps and infusion sets. Refer to the Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.	Same
Contraindication	The reservoir is contraindicated for the infusion of blood and blood products.	The reservoir is contraindicated for the infusion of blood and blood products.	Same
Duration of Use	MiniMed Reservoir 1.8mL (MMT-326A) = Up to 3 days MiniMed Reservoir 3.0mL (MMT-332A) = Up to 3 days Extended Reservoir (MMT-342, MMT-342G) = Up to 7 days	MiniMed Reservoir 1.8mL (MMT-326A) = Up to 3 days MiniMed Reservoir 3.0mL (MMT-332A) = Up to 3 days Extended Reservoir (MMT-342, MMT-342G) = Up to 7 days	Same
Principle of Operation	Movable stopper	Movable stopper	Same
Nominal Volume	MiniMed Reservoir 1.8mL (MMT-326A) = 1.8mL (1.5 usable) MiniMed Reservoir 3.0mL (MMT-332A) = 3.0mL (2.7 usable) Extended Reservoir (MMT-342, MMT-342G) = 3.0mL (2.7 usable)	MiniMed Reservoir 1.8mL (MMT-326A, MMT-326AT) = 1.8mL (1.5 usable) MiniMed Reservoir 3.0mL (MMT-332A) = 3.0mL (2.7 usable) Extended Reservoir (MMT-342, MMT-342G) = 3.0mL (2.7 usable)	Same
Filling Method	Transfer guard with needle	Transfer guard with needle	Same
Reservoir Length (barrel)	MiniMed Reservoir 1.8mL (MMT-326A) = 3.19cm (1.255 in) MiniMed Reservoir 3.0mL (MMT-332A) = 4.34cm (1.707in)	MiniMed Reservoir 1.8mL (MMT-326A) = 3.19cm (1.255 in) MiniMed Reservoir 3.0mL (MMT-332A) = 4.34cm (1.707in)	Same

Specification	Predicate Devices **MiniMed Reservoir 1.8mL (MMT-326A, K001828)** **MiniMed Reservoir 3.0mL (MMT-332A, K032005)** **Extended Reservoir (MMT-342, MMT-342G, K210714)**	Subject Devices **MiniMed Reservoir 1.8mL (MMT-326A, K001828)** **MiniMed Reservoir 3.0mL (MMT-332A, K032005)** **Extended Reservoir (MMT-342, MMT-342G, K210714)**	Comparison
	Extended Reservoir (MMT-342, MMT-342G) = 4.34cm (1.707in)	Extended Reservoir (MMT-342, MMT-342G) = 4.34cm (1.707in)	
Filling Needle Material	304 stainless steel	304 stainless steel	Same
Filling Needle Length	0.74in	0.74in	Same
Filling Needle Gauge	26 gauge	26 gauge	Same
Needle Tip Configuration	Beveled	Beveled	Same
Biocompatibility	Non-toxic, non-pyrogenic; meets ISO 10993	Non-toxic, non-pyrogenic; meets ISO 10993	Same
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same
Sterilization Cycle	Cycle 415	Cycle 415 Cycle 86	**Different:** The Cycle parameters have been changed to optimize EO sterilization.
Sterilization Location	Steri-Tech, Inc., Puerto Rico	Steri-Tech, Inc., Puerto Rico Sterigenics US, LLC, Atlanta, GA	**Different**: The Sterigenics site has been added as an alternate sterilization facility.
Sterilization Release	Biological Indicators (BI)	Biological Indicators (BI) Parametric Release	**Different:** The parametric release process has been qualified as an additional release process
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Specific Drug Use	Medication labeled for subcutaneous administration	Medication labeled for subcutaneous administration	Same

Specification	Predicate Devices MiniMed Reservoir 1.8mL (MMT-326A, K001828) MiniMed Reservoir 3.0mL (MMT-332A, K032005) Extended Reservoir (MMT-342, MMT-342G, K210714)	Subject Devices MiniMed Reservoir 1.8mL (MMT-326A, K001828) MiniMed Reservoir 3.0mL (MMT-332A, K032005) Extended Reservoir (MMT-342, MMT-342G, K210714)	Comparison
Insulin Compatibility	Humalog®/Novolog®	Humalog®/Novolog®	Same

4. Performance Data

Medtronic performed verification testing to support the addition of a new sterilization facility and the implementation of an optimized EO sterilization cycle. As part of the verification testing, the impact of the sterilization change on the product's material, performance and shelf-life was evaluated. The testing was performed on MMT-332A since the subject devices have the same hardware design, materials, and attributes as the predicate device. The test results demonstrate the subject devices met all the product requirements and specifications of the predicate devices.

Additionally, Medtronic performed a risk analysis assessment to evaluate and identify potential new hazards and failure modes related to the use of the reservoirs following sterilization at the new site under the new cycle parameters. Based on the results, Medtronic concludes that the use of the reservoirs sterilized at the new site under the optimized EO cycle does not raise any additional questions of safety and effectiveness.

5. Substantial Equivalence

Based on the 510(k) summary information provided herein, Medtronic concludes that the subject devices are substantially equivalent to the predicate devices in intended use, safety, effectiveness, and underlying scientific and operating principles. The fundamental difference between the subject devices and the predicate devices is limited to an additional sterilization site and optimized EO sterilization cycle.

6. Conclusions

The proposed change is limited to qualifying an additional sterilization site and optimized EO sterilization cycle for the reservoirs. The reservoirs have the same intended use, hardware design, technological characteristics (i.e., material, chemical composition, energy source), storage reservoir capacity (1.8mL or 3.0mL), and principle of operation as the predicate devices. Medtronic evaluated and performed required verification testing to support the additional sterilization site and optimized EO sterilization cycle. The test results demonstrated that the reservoirs met all the product requirements and intended use.

Additionally, Medtronic performed a risk analysis assessment to evaluate and identify potential new hazards and failure modes related to the use of the reservoirs following sterilization at the new site under the new sterilization cycle parameters. Based on the results, Medtronic concludes the reservoirs can be sterilized at the additional facility using the optimized parameters for EO sterilization cycle. This change does not raise additional questions of safety and effectiveness when compared to Medtronic's currently marketed predicate devices. Therefore, the subject devices are substantially equivalent to the legally marketed predicate devices.