April 6, 2022

Medtronic MiniMed, Inc.
Christina Rowe
Senior Regulatory Affairs Manager
18000 Devonshire Street
Northridge, California 91325

Re: K210714
Trade/Device Name: Extended Reservoir
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LZG
Dated: December 17, 2021
Received: December 17, 2021

Dear Christina Rowe:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210714

Device Name
Extended Reservoir

Indications for Use *(Describe)*
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.

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.

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510(k) Summary

Extended Reservoir

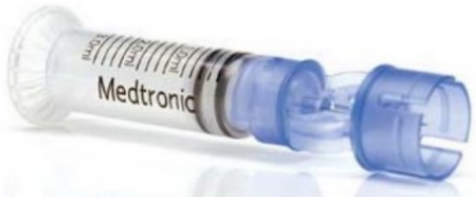
Table 1-1: General Information

Device Trade/ Generic Name	Extended Reservoir
Predicate Device Name and Model ID	Medtronic MiniMed Paradigm Reservoir MMT-332A (3.0mL)
Predicate 510(K) Number	**K032005**
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, Inc. 18000 Devonshire Street Northridge, CA 91325 USA
Manufacturing Facility	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	Christina Rowe Senior Regulatory Affairs Manager Tel: (818) 942-4875 Fax: (818) 576-6273 Email : christina.rowe@medtronic.com
Secondary Contact Information	Darin S. Oppenheimer Senior Regulatory Affairs Director Tel: (609) 500-9672 Email: darin.s.oppenheimer@medtronic.com

1. Device Description

Extended Reservoir (herein referred to as “EWR” or “MMT-342”) is a sterile medication container (**Figure 1-1**) designed for single use.

Figure 1-1: Extended Reservoir with Transfer Guard



The Extended Reservoir (MMT-342) 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 Extended Reservoir (subject device) 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.

Principle of Operations

The subject device (MMT-342) has the same principle of operation as the predicate device (MMT-332A). Same as the predicate device (MMT-332A), the subject device (MMT-342) is designed to mechanically connect to compatible infusion sets (Medtronic Extended Wear Infusion Sets, i.e., EWIS). The reservoir is 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 subject device (MMT-342) shares all attributes of the predicate device (MMT-332A), including the same intended use, same technological characteristics (i.e., hardware design, material, chemical composition, energy source etc.), same 3.0mL storage reservoir, and has the same principle of operation as the marketed predicate device (MMT-332A cleared by FDA under **K032005**). The change is limited to extending the duration of the reservoirs use (from up to 3 days to up to 7 days).

An exploded view of the subject device (MMT-342) is presented in **Figure 1-2** while its components are provided in **Table 1-2**.

Figure 1-2: Extended Reservoir with Transfer Guard

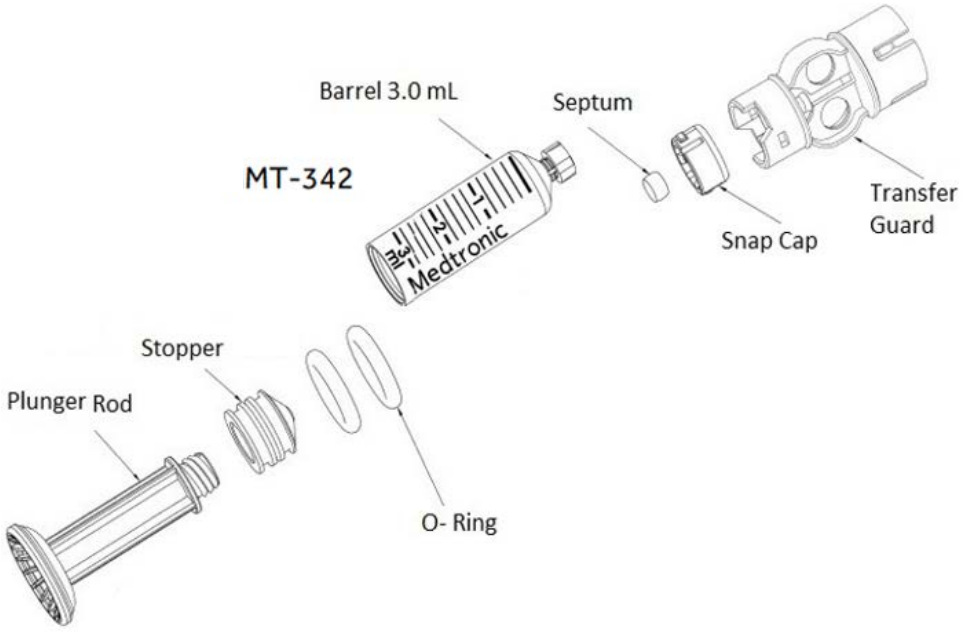


Table 1-2: Reservoir Components Definitions

Component	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.
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.
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
Barrel	Stores the insulin.

2. Indications 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.

3. Technological Characteristics and Substantial Equivalence (SE)

The scope of the subject device (MMT-342) is limited to extending the duration of reservoir use (from up to 3 days to up to 7 days). The hardware design of the subject device MMT-342 is the same as the predicate device MMT-332A (**K032005**). Please note that there are no changes in the hardware design, manufacturing, packaging, sterilization processes, fluid capacity, insulin compatibility, reservoir assembly, between the predicate MMT-332A (**K032005**) and the subject device (MMT-342). The change is limited to extending the duration of reservoir use (from up to 3 days to up to 7 days) as shown in **Table 1-3**.

A Substantially Equivalent (SE) chart of the similarities and differences between the predicate device (MMT-332A) and the subject device (MMT-342) is shown in **Table 1-3**.

Table 1-3: Comparision of Predicate Device MiniMed Reservoir MMT-332A (K032005) to the Subject Device Extended Reservoir MMT-342

Specification	MiniMed Reservoir (Predicate Device) MMT-332A (K032005)	Extended Reservoir (Subject Device) MMT-342	Comparison
Type of Device	User-filled Reservoir	User-filled Reservoir	Same
Intended Use	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.	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.	**Different**: the product name and model number for EWR is listed. A more specific statement about compatible insulins / infusion sets is also described.
Contraindication	This reservoir is contraindicated for the infusion of blood or blood products.	This reservoir is contraindicated for the infusion of blood or blood products.	Same
Duration of use	Up to 3 days	Up to 7 days	**Different**: The duration of use has increased from 3 to 7 days.
Principle of Operations	Movable stopper	Movable stopper	Same
Nominal volume	3.0mL (2.7mL usable)	3.0mL (2.7mL usable)	Same
Filling Method	Transfer Guard with needle	Transfer Guard with needle	Same
Reservoir Length (Barrel)	4.34cm (1.707in)	4.34cm (1.707in)	Same
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	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Specific Drug Use	Medication labeled for subcutaneous administration	Medication labeled for subcutaneous administration	Same
Insulin Compatibility	Humalog®/Novolog®	Humalog®/Novolog®	Same

Plunger Material	Polypropylene (only for filling)	Polypropylene (only for filling)	Same
Barrel Material and Markings	Polypropylene 0.2mL increments	Polypropylene 0.2mL increments	Same
Barrel Transparency	Translucent	Translucent	Same
Shelf Life	3 years	3 years	Same
Packaging	10 each / customer box 720 each / shipper case	10 each / customer box 720 each / shipper case	Same

For the reviewer's convenience, Medtronic is providing a reservoir components comparison (**Table 1-4**) between the predicate device (MMT-332A) and the subject device (MMT-342). The comparison demonstrates that the subject device (MMT-342) utilizes the same hardware design elements as the predicate device (MMT-332A) and highlights the fundamental difference limited to extending the duration of reservoir use (from up to 3 days to up to 7 days).

Table 1-4: Reservoir Components Comparison

Reservoir Design Elements	Predicate Device: MiniMed Reservoir MMT-332A (K032005)	Subject Device: Extended Reservoir MMT-342	Comparison
Model Number	**MMT-332A**	**MMT-342**	
Volume	3.0mL	3.0mL	**Same**
Part Number	7005317J002	7005317J002	**Same**
Plunger Rod	6014747-006	6014747-006	**Same**
Ribbed Stopper	6015400-002	6015400-002	**Same**
O-Ring	D60144995-005	D60144995-005	**Same**
Barrel	7005291J003	7005291J003	**Same**
Lubricant	D8062007-001	D8062007-001	**Same**
Septum	D6014713-004	D6014713-004	**Same**
Transfer Guard	7005176J-001	7005176J-001	**Same**
Snap Cap	6015129-001	6015129-001	**Same**

4. Performance Data

Medtronic performed verification testing to support extending the duration of the reservoirs use (from up to 3 days to up to 7 days). The verification testing was performed on MMT-332A (predicate device) since the MMT-342 (subject device) has the same hardware design, materials, and attributes as the predicate device (MMT-332A) except for extending the duration of the reservoirs use (from up to 3 days to up to 7 days). The test results demonstrate that MMT-342 (subject device) met all the product requirements and specifications of MMT-332A (predicate

device). Additionally, Medtronic performed a risk analysis assessment to evaluate and identify potentially new hazards and failure modes related to the use of MMT-342 (subject device) for the extended duration (up to 7 days).

Based on the results, Medtronic concludes that the use of MMT-342 (subject device) for the extended duration of up to 7 days 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 MMT-342 (subject device), is substantially equivalent to MMT-332A (predicate device) in its intended use, safety, effectiveness, and underlying scientific and operating principles. Medtronic would like to reiterate the fundamental difference between the MMT-332A (predicate) and MMT-342 (subject device) is limited to extending the reservoir duration of use (from up to 3 days to up to 7 days).

6. Conclusions

In conclusion, the proposed change is limited to extending the reservoir duration of use (from up to 3 days to up to 7 days). As stated previously, MMT-342 (subject device) has the same intended use, same hardware design, same technological characteristics (i.e., hardware design, material, chemical composition, energy source), same 3.0mL storage reservoir, and same principle of operation as the MMT-332A (predicate device). Medtronic performed verification testing to support extending the reservoir duration of use (up to 7 days). The test results demonstrated that MMT-342 (subject device) met all the product requirements and intended use. Additionally, Medtronic performed risk analysis assessment to identify potential new hazards and failure modes related to the extended duration of use of MMT-342 (subject device) compared to MMT-332A (predicate device).

Based on the results, Medtronic concludes MMT-342 (subject device) can have an extended duration of use (up to 7 days) and does not raise any additional questions of safety and effectiveness when compared to the MMT-332A (predicate device). Therefore, the subject device (MMT-342) is substantially equivalent to the legally marketed predicate device (MMT-332A (**K032005**)).