July 16, 2021

Unomedical A/S
Lone Vestergaard Jepsen
Regulatory Affairs Specialist
Aaholmvej 1-3
Osted, Lejre 4320
Denmark

Re: K210544
Trade/Device Name: Medtronic Extended infusion set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 5, 2021
Received: May 10, 2021

Dear Lone Vestergaard Jepsen:

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 -S

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)*
K210544

Device Name
Medtronic Extended infusion set

Indications for Use *(Describe)*
The Medtronic Extended infusion set is indicated for subcutaneous infusion of medication administered by an external pump. The infusion set is indicated for single use.

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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5. 510(k) Summary

Device Name: Medtronic Extended infusion set

5.1 Submission Sponsor

Unomedical a/s

Aaholmvej 1-3, Osted

DK-4320 Lejre,

Denmark

Primary contact: Lone Sylvest Vestergaard Jepsen

Title: Regulatory Affairs Specialist

Secondary contact: Mette Busk Henningsen

Title: Regulatory Affairs Specialist

5.2 Date Prepared

July 13, 2021

5.3 Device Identification

Trade/Proprietary Name:	Medtronic Extended infusion set
Common/Usual Name:	Set, Administration, Intravascular
Classification Name:	Intravascular administration set
Regulation Number:	880.5440
Product Code:	FPA, Intravascular administration set
Device Class:	Class II
Classification Panel:	General Hospital

5.4 Legally Marketed Predicate Device(s)

Table 5.1: Legally Marketed Predicate Device.

Device Name	510(k) No.	Product Code	Classification Regulation	Sponsor
MiniMed™ Mio™ Advance Infusion Set	K173879	FPA	880.5440	Unomedical

5.5 Indication for Use Statement

The Medtronic Extended infusion set is indicated for subcutaneous infusion of medication administered by an external pump. The infusion set is indicated for single use.

5.6 Device Description

The Medtronic Extended infusion set manufactured by Unomedical a/s is a sterile, non-pyrogenic, single use subcutaneous infusion set which includes a 90-degree soft cannula. It is delivered ready to use in a pre-loaded insertion device with automatic needle retraction. The product is indicated for subcutaneous infusion of medication administered by an external pump.

The insertion needle and soft cannula of the Medtronic Extended infusion set are hidden from the user before, during and after insertion of the soft cannula. This feature helps prevent needle stick injuries as the device does not require loading with the needle by the user, the needle is then automatically retracted after use.

The Medtronic Extended infusion set is designed to be used with a Medtronic Insulin infusion pump for up to 7 days.

5.7 Substantial Equivalence

The following table compares the Medtronic Extended infusion set to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The proposed device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5.2: Comparison of Characteristics.

Manufacturer	**Unomedical a/s**	**Unomedical a/s**	**Device Comparison**
Trade Name	MiniMed™ Mio™ Advance Infusion Sets (predicate device)	Medtronic Extended infusion set (proposed device)	N/A
510(k) Number	K173879	K210544	N/A
Product Code	FPA	FPA	Same
Regulation Number	880.5440	880.5440	Same
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
Indications for Use	The MiniMed™ Mio™ Advance Infusion Set is indicated for subcutaneous infusion of medication administered by an external pump.	The Medtronic Extended infusion set is indicated for the subcutaneous infusion of medication from an external pump. The infusion set is indicated for single use	Same “The infusion set is indicated for single use” has been moved from “Warnings” section for clarification.
Mechanism of Action	The MiniMed™ Mio™ Advance Infusion Set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	The Medtronic Extended infusion set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	Same

Manufacturer	Unomedical a/s	Unomedical a/s	Device Comparison
Trade Name	MiniMed™ Mio™ Advance Infusion Sets (predicate device)	Medtronic Extended infusion set (proposed device)	N/A
Technology Overview	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle. • insertion of soft cannula: 2 user steps for insertion: remove protective cap for base and press release button • The Base Set in MiniMed™ Mio™ Advance infusion set is made of two components, the Fluid Part and the Base Part • The MiniMed™ Mio™ Advance infusion set is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. This mechanism allows the needle to be hidden from the user and/or caregiver before and after insertion.	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle. • insertion of soft cannula: 2 user steps for insertion: remove protective cap for base and press release button • The Base Set in Medtronic Extended infusion set is made of two components, the Fluid Part and the Base Part • The Medtronic Extended infusion set is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. This mechanism allows the needle to be hidden from the user and/or caregiver before and after insertion.	**Serter:** Visually identical, with identical mode of operation. The design of the Medtronic Extended infusion set is detailed in section 11 of this 510K.
	Administration Set: The administration set attaches to the reservoir by means of a “tubing connector”, and subcutaneously into the user through an indwelling cannula made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The indwelling cannula is introduced into the subcutaneous tissue by a removable 27-gauge introducer needle (catheter) made of AISI 304 stainless steel.	**Administration Set:** The administration set attaches to the reservoir by means of a “tubing connector”, and subcutaneously into the user through an indwelling cannula made of polytetrafluoroethylene (PTFE). The tubing connector and the adhesive patch are updated to facilitate an extended wear time. The tubing is made of three layers: the inner layer is polypropylene; the middle layer is polyethylene and the outer is polyurethane. The indwelling cannula is introduced into the subcutaneous tissue by a removable 27-gauge introducer needle (catheter) made of AISI 304 stainless steel.	**Administration Set:** Same technology

Manufacturer	Unomedical a/s	Unomedical a/s	Device Comparison
Trade Name	MiniMed™ Mio™ Advance Infusion Sets (predicate device)	Medtronic Extended infusion set (proposed device)	N/A
Anatomical Location	Standard recommended sites for subcutaneous infusion of medication i.e. subcutaneous sites are selected based on the presence of adequate adipose tissue. The choice of insertion site depends on treatment and patient specific factors as recommended by HCP. Preference is given to sites that do not affect the patient's mobility, the insertion site has to be free of skin irritation and inflammation such as redness, scar tissue and bleeding. Site selection: the abdomen, in a roughly semicircular area around and below the umbilicus is preferred as an application site. Other insertion sites include the upper leg, upper buttocks, hips, upper arms and lower back and occasionally the chest when other sites have edema. The area to place the infusion set is particularly important in patients with many years of use, since the overuse of skin sites has an influence on absorption variability.	Standard recommended sites for subcutaneous infusion of medication i.e. subcutaneous sites are selected based on the presence of adequate adipose tissue. The choice of insertion site depends on treatment and patient specific factors as recommended by HCP. Preference is given to sites that do not affect the patient's mobility, the insertion site has to be free of skin irritation and inflammation such as redness, scar tissue and bleeding. Site selection: the abdomen, in a roughly semicircular area around and below the umbilicus is preferred as an application site. Other insertion sites include the upper leg, upper buttocks, hips, upper arms and lower back and occasionally the chest when other sites have edema. The area to place the infusion set is particularly important in patients with many years of use, since the overuse of skin sites has an influence on absorption variability.	Same
Material	Materials include: Polypropylene, polyoxymethylene, stainless steel, polytetraflouroethylene, nonwoven polyester/polyacrylate, polyethylene, silicone, Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS), Terlux 2802 HD, transp., medical grade paper, polycarbonate	Materials include: Polypropylene, polyoxymethylene, stainless steel, polytetraflouroethylene, nonwoven polyester/polyacrylate, polyethylene, silicone, Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS), Terlux 2802 HD, transp., medical grade paper, polycarbonate, polyvinylalcohol	Essentially identical, with the notable addition of polyvinylalcohol. Appropriate biocompatibility testing has been conducted on the proposed device.
Sterile	Yes – EO – SAL 10^{-6}	Yes – EO – SAL 10^{-6}	Same
Single-Use	Yes	Yes	Same
Shelf Life	3 years	2 years	Shelf life reduced
Complies with ISO 10993-1	Yes	Yes	Same

Manufacturer	Unomedical a/s	Unomedical a/s	Device Comparison
Trade Name	MiniMed™ Mio™ Advance Infusion Sets (predicate device)	Medtronic Extended infusion set (proposed device)	N/A
Soft Cannula Length	6 and 9 mm	6 and 9 mm	Same
Tubing: **ID** **OD**	 0.385 mm, 1.50 mm	 0.406 mm, 1.52 mm	Change due to added middle layer in tubing. Substantially equivalent based on bench testing.
Soft Cannula OD	0.68 mm	0.68 mm	Same
Needle Gauge	27 gauge	27 gauge	Same
Tubing Length	46, 60 and 110 cm	46, 60, 80 and 110 cm	Same tubing length range. Added intermediate size.
Angle of Insertion	90 degrees, perpendicular	90 degrees, perpendicular	Same
Insertion Method	Pre–loaded insertion device with automatic needle retraction. The insertion needle and soft cannula are hidden from the user before, during and after insertion of the soft cannula.	Pre–loaded insertion device with automatic needle retraction. The insertion needle and soft cannula are hidden from the user before, during and after insertion of the soft cannula.	Same
Time of Use	Up to 72 hours (3 days)	Up to 168 hours (7 days)	Recommended maximum wear time extended. The claim is supported by the clinical performance testing (see section 20).

5.8 Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Medtronic Extended infusion set and in showing substantial equivalence to the predicate device, Unomedical completed a number of non-clinical performance tests. The Medtronic Extended infusion set meets all the requirements for overall design, sterilization, biocompatibility, and usability confirming that the design output meets the design inputs and specifications for the device.

The Medtronic Extended infusion set has met the requirements for testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

Testing:

1. Functional tests
    - Leak/Tightness
    - Flow (Occlusion)
    - Tensile tests of introducer needle from needle hub, tubing connections, soft cannula from Fluid Part assembly, adhesive tape from base, connector from base, connector needle from connector
    - Strength tests of Fluid Part assembly from base assembly, base assembly from cylinder, serter activation force (intended and unintended), disassembly of cylinder from cover
    - Serter functionality tests

2. Packaging tests:
    - Dynamic and Visual Peel Test
    - Print on Packaging and labelling

3. Transportation Tests:
    - Transportation tests general

4. Compatibility Tests:
    - Drug and Device Compatibility

5. Dimensional Tests:
    - Distance soft cannula to set
    - Distance of introducer needle bevel to soft cannula
    - Length of tubes

6. Biocompatibility Testing in accordance with ISO 10993-1
7. EO/ECH residuals Testing
8. Pyrogen/Endotoxin Testing
9. Shelf life Testing
10. Sterilization Testing
11. Usability Testing

5.9 Clinical Evaluation

A clinical study has been conducted in the US. A total of 291 subjects were enrolled at 15 investigational centers.

The results of the clinical study demonstrated that the use of the Medtronic Extended infusion set was safe and effective for the full 7 days. There were no device-related serious adverse events.

5.10 Standards Used

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

ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11737-1:2018, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

ISO 11737-2:2019, Sterilization of medical devices – Microbiological methods – Part 2: Test of sterility performed in the definition, validation, and maintenance of a sterilization process

ASTM F1980-16: 2016, Standard Guide for Accelerated Aging Sterile Barrier Systems for Medical Devices

EN 556-1:2001 & EN556-1/AC:2006, “Sterilization of medical devices – Requirements for medical devices to be designated “Sterile”- Part 1: Requirements for terminally sterilized medical devices”

EN ISO 11138-1: 2017, “Sterilization of heath care products – Biological indicators – Part 1: General Requirements”

EN ISO 11138-2: 2017, “Sterilization of heath care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes”

ISO 11607-1:2019, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 11607-2:2019, Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes

ISO 15223-1:2016, Medical devices – Symbols to be used with medical devices labels, labeling, and information to be supplied – Part 1: General requirements

EN 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 10993-6:2016, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation

EN ISO 10993-7:2008 & EN ISO 10993-7/AC:2009, Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals

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

EN 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

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

EN ISO 8536-8:2015 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed

ISO 8536-9:2015 Infusion Equipment for Medical Use – Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment

ASTM D4169-16 – Standard Practice for Performance Testing of Shipping Containers and Systems

IEC 62366-1:2015/AC, “Medical devices – Part 1: Application of usability engineering to medical devices”

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

5.11 Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The Medtronic Extended infusion set, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.