March 5, 2018

Unomedical A/S
% Deirdre Barrow
Senior Consultant, Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road
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Austin, Texas 78746

Re: K173879
Trade/Device Name: MiniMed™ Mio™ Advance infusion set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: December 21, 2017
Received: December 21, 2017

Dear Deirdre Barrow:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173879

Device Name
MiniMed™ Mio™ Advance infusion set

Indications for Use *(Describe)*
The MiniMed™ Mio™ Advance infusion set is indicated for subcutaneous infusion of medication administered by an external pump.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K 173879

1. Submission Sponsor

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Contact: Deirdre Barrow

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3. Date Prepared

December 21, 2017

4. Device Identification

Trade/Proprietary Name: MiniMed™ Mio™ Advance 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. Legally Marketed Predicate Device(s)

Table 5A: Legally Marketed Predicate

Device Name	510(k) No.	Product Code	Classification Regulation	Sponsor
Unomedical Inset™ Subcutaneous Infusion Set (formerly known as the Unomedical Monica Infusion Set)	K032854	FPA	880.5440	Unomedical

6. Indication for Use Statement

The MiniMed™ Mio™ Advance infusion set is indicated for subcutaneous infusion of medication administered by an external pump.

7. Device Description

The MiniMed™ Mio™ Advance infusion set manufactured by Unomedical 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.

The insertion needle and soft cannula of the MiniMed™ Mio™ Advance infusion set are hidden from the user before, during and after insertion of the soft cannula. This feature helps prevents 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 MiniMed™ Mio™ Advance infusion set will include a 27-gauge introducer needle, and will be available in two different soft cannula lengths of 6 and 9mm and three different tubing lengths of 46, 60 and 110cm. The tube set is available in P-Cap assembly or luer lock.

The MiniMed™ Mio™ Advance infusion set has been updated from the predicate K032854 Unomedical Inset™ Subcutaneous Infusion Set by the same manufacturer. The only modifications were made to the inserter component and include a single molded component rather than two pieces, and the addition of a needle safety shield. The connector and tubing of the tubing set remains unchanged.

8. Substantial Equivalence Discussion

The following table compares the MiniMed™ Mio™ Advance infusion set to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The predicate device has been updated to include a needle safety shield, and to be molded as one piece rather than two, no other changes have been made. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The differences in technological characteristics does not raise different questions of safety or effectiveness.

Table 5A – Comparison of Characteristics

Manufacturer	**Unomedical**	**Unomedical**	**Device Comparison**
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
510(k) Number	Unknown	K032854	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 Unomedical Inset™ Subcutaneous Infusion Sets are indicated for the subcutaneous infusion of medication from an external pump. .	Same
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 Unomedical Inset™ Subcutaneous Infusion Set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	Same
Technology Overview	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle.	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle.	**Serter:** • Same angle of insertion and use of introducer needle and cannula

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	• insertion of soft cannula: 2 user steps for insertion: remove protective cap for base and press release button	• insertion of soft cannula: 3 manual user steps for insertion: loading, inserting and retraction.	• Both devices use an insertion device to insert the soft cannula, the proposed device has an insertion mechanism preloaded and ready for insertion by simply pressing the activation button after removing the safeguard. This technical difference is not clinically significant as while this additional safety feature does have a minor impact upon the method of operation of the device it does not introduce any different questions of safety or effectiveness.
	• The Base Set in MiniMed™ Mio™ Advance infusion set is made of two components, the Fluid Part and the Base Part	• The Base Set used in Unomedical inset™ is molded as one	• The fluid part of the MiniMed™ Mio™ Advance infusion set assembly is inserted into the base assembly (on body). This step is not required for the Unomedical inset™ infusion set. This technical difference is not clinically significant as the additional required step for the proposed device does not significantly impact the method of operation

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	• The MiniMed™ Mio™ Advance infusion set is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. The newly developed mechanism allows the needle to be hidden from the user and/or caregiver before and after insertion.	• The Unomedical Inset™ Subcutaneous Infusion Set does not have a mechanism for automatic needle retraction and the needle is visible to the user.	of the device • The insertion needle and soft cannula of the MiniMed™ Mio™ Advance infusion set are hidden from the user before, during and after insertion of the soft cannula. This feature helps prevent needle stick injuries. This technical difference does not introduce any new questions regarding safety and efficacy of the device. The additional safety feature does not impact the method of operation of the device.
	Administration Set: The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in to the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The indwelling catheter	**Administration Set:** The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in to the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is	Same technology used in both devices for the administration set.

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	is introduced into the subcutaneous tissue by a removable 27-gauge introducer needle (cannula) made of AISI 304 stainless steel.	is introduced into the subcutaneous tissue by a removable 27-gauge introducer needle (cannula) made of AISI 304 stainless steel.	
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	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 umbilicus is preferred as an application site. Other insertion sites include the upper leg, upper buttocks, hips, upper arms and	Same

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	occasionally the chest when others sites have edema. The area to place the infusion set is particularly important in patients with many years use, since the overuse of skin sites has an influence on absorption variability.	lower back and occasionally the chest when others sites have edema. The area to place the infusion set is particularly important in patients with many years use, since the overuse of skin sites has an influence on absorption variability.	
Material	Materials include: Polypropylene, polyoxymethylene, copolyester/polycarbonate alloy, Eastalloy DA003-8999K polymer stainless steel, polytetrafluoroethylene, nonwoven polyester/polyacrylate, polyethylene, silicone, Methyl Methacrylate Acrylonitrile Butadiene Styrene(MABS), Terlux 2802 HD, transp., medical grade paper, polycarbonate	Materials include: Polypropylene, Stainless Steel, Polyethylene, Polyurethane, Silicone, Polycarbonate, Polytetrafluoroethylene, Methyl Methacrylate Acrylonitrile Butadiene Styrene(MABS), Terlux 2802 HD, transp., Medical Grade Paper, UV-cured Glue, Color Pigments	No significant difference as the infusion set which remains on the patient is the same as the predicate device and appropriate biocompatibility testing has been conducted on the insertion device.
Sterile	Yes – EO – SAL 10^{-6}	Yes – EO – SAL 10^{-6}	Same
Single-Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Complies with ISO 10993-1	Yes	Yes	Same

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	MiniMed™ Mio™ Advance infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
Soft Cannula Length	6 and 9mm	6 and 9mm	Same
Tubing: **ID** **OD**	 0.385 mm, 1.50 mm	 0.385 mm, 1.50 mm	Same
Soft Cannula OD	0.68mm	0.68mm	Same
Needle Gauge	27 gauge	27 gauge	Same
Tubing Length	46 cm, 60 cm and 110 cm	60 and 110 cm	An additional tubing length of 46 cm has been made available for the proposed device
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.	Insertion device, which enables the user not to place the soft cannula in the tissue manually	Similar in that both devices allow for the patient to not have to insert the device in the tissue manually – the proposed device includes an additional mechanism so that the patient does not need to see the needle or cannula at any stage of the process and has an automatic needle retraction to help ensure needle safety
Time of Use	Up to 72 hours	Up to 72 hours	Same

The indications for use statement and the intended use of the subject device are identical to the predicate device. The differences between the subject device and the predicate device are:

1. The predicate inserter was comprised of 2 pieces, the subject inserter is now molded as 1 piece
2. A needle safety shield has been added to the inserter.

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of MiniMed™ Mio™ Advance infusion set, Unomedical completed a number of non-clinical performance tests. The MiniMed™ Mio™ Advance 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 tube set is identical to that used in the predicate, additional testing was not performed to validate these components.

The MiniMed™ Mio™ Advance 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:

- Functional tests:
    - Tensile tests of introducer needle from needle hub, soft cannula from Fluid Part assembly, Fluid Part assembly from base assembly, connector needle from cannula housing,
    - Serter functionality tests
- Packaging tests
    - Dynamic and Visual Peel Test
    - Print on Packaging and labelling
- Transportation Tests in accordance with ASTM D4169-16
- Dimensional Tests
    - Distance soft cannula to set
    - Distance of introducer needle bevel to soft cannula
    - Length of tubes
- Cytotoxicity Testing in accordance with ISO 10993-5
- Sensitization Testing in accordance with ISO 10993-10
- Irritation Sensitivity Testing in accordance with ISO 10993-10
- Acute Systemic Toxicity testing in accordance with ISO 10993-11
- Pyrogen/Endotoxin Testing in accordance with ISO 11737-1
- Shelf life Testing in accordance with ISO 11607
- Sterilization Testing in accordance with ISO 11135:2014
- Usability Testing In accordance with IEC 62366-1:2015

Standards:

ASTM F1980:2011; Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

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

ISO 10993-1:2009; Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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

ISO 10993-11:2006; Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

ISO 10993-18:2009; Biological evaluation of medical devices. Chemical characterization of materials

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

ISO 11607-1:2009; Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2:2006; Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

ISO 11737-1:2006; Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

ISO 11737-2:2009; Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 14971:2012; Medical devices. Application of risk management to medical devices

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

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 (Swedish Standard)

EN ISO 11138-1: 2006; Sterilization of health care products -- Biological indicators -- Part 1: General requirements

EN ISO 11138-2: 2006; Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes

EN 62366-1:2015/AC; Medical devices -- Part 1: Application of usability engineering to medical devices

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

The MiniMed™ Mio™ Advance infusion set is substantially equivalent to the predicate device.