DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 10, 2016

Unomedical A/S
Ms. Cindie Vandfeldt
Regulatory Affairs Specialist
Aaholmvej 1-3, Osted
Roskilde, DK-4320
DENMARK

Re: K160648
Trade/Device Name: MiniMed Quick-Set®
MiniMed Sure-T®
MiniMed Silhouette®
MiniMed Mio®
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 28, 2016
Received: June 30, 2016

Dear Ms. Vandfeldt:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160648

Device Name
MiniMed Quick-Set®; MiniMed Sure-T®; MiniMed Silhouette®; MiniMed Mio®

Indications for Use *(Describe)*
These sets are intended to be used with Medtronic Paradigm Insulin Subcutaneous Infusion Pumps for continuous subcutaneous insulin infusion by patients or caregivers in the home environment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

"510(K) SUMMARY" K160648

Submitted by/Contact Person: John M. Lindskog
General Manager Unomedical A/S Infusion Devices Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark
Telephone: + 45 46 42 78 10 (CET 0800-1700)
Fax: + 45 46 42 78 65
E-mail: JML@unomedical.com Date Prepared: February 20, 2016

1.0 Trade/Proprietary Names:
- 1.1 MiniMed Quick-Set®
- 1.2 MiniMed Sure-T®
- 1.3 MiniMed Silhouette®
- 1.4 MiniMed Mio®

2.0 Common/Usual Name Subcutaneous Insulin Infusion Set

3.0 Classification Name: Intravascular Administration Set

Classification: Class: II
Panel: 80
Product Code: FPA
Cite: 21 CFR 880.5440

4.0 Purpose of Submission
To market sets in which the membrane material of the proprietary Medtronic P-Cap Connector was upgraded to enhance the ability of the membrane to remain gas permeable and retain venting capability when wet.

5.0 Substantial Equivalence
The subject devices are substantially equivalent to the Subcutaneous Insulin Infusion Sets cleared under the following 510(k)s:
- 5.1 K011071– Medtronic Quick-Set® Paradigm® Subcutaneous Insulin Infusion Set
- 5.2 K041545 – Contact Detach (Marketed as Medtronic Sure-T® Paradigm® Subcutaneous Insulin Infusion Set)
- 5.3 K002138 Medtronic Silhouette® Paradigm® Subcutaneous Insulin Infusion Set
- 5.4 K032854 – Unomedical Monica Infusion Set – (Marketed as Medtronic Mio® Subcutaneous Infusion Insulin Set)

Top

6.0 Device Description

6.1 General Description

All of the Subcutaneous Insulin Infusion Sets are sterile, non-pyrogenic, single use subcutaneous infusion sets. Each set design has two main components provided for each device. The first is a subcutaneous indwelling Cannula component and the second is a tubing set component. For all sets, the connection of the indwelling cannula to the tubing set is made using a proprietary plastic “click-lock" connector system that enables the disconnection.

The Cannula component has an adhesive backed fixation tape that is attached directly to the patient’s skin over the injection site. The cannula is sometimes provided separately from, and sometimes provided pre-attached to the tubing, but in all cases is able to be detached from the tubing to temporarily discontinue the infusion or to replace the cannula independent of the tubing. Some of the cannulas are stainless steel needles and others are soft catheters that are inserted with stainless steel insertion needles that are then removed and discarded. All except the Mio® are manually inserted into the subcutaneous tissue. The Mio® is provided integrated in an automated inserter.

The second main component of the set is the tubing set. The infusion set tubing for all sets, except for the QuickSet, are comprised of a co-extruded tube with a stainless steel needle incorporated into the male portion of the proprietary plastic "click-lock" connector at the patient that punctures and penetrates a septum in the cannula connector, creating an aseptic fluid path to the user and that enables the connection and disconnection. The QuickSet tubing connects and disconnects with a snap on connection to the cannula component. The sets are offered in different lengths of tubing. As these sets are specifically designed only to be used with the commercially available MiniMed Paradigm Insulin Infusion pumps which use a MiniMed Paradigm medication reservoir with a proprietary pump reservoir connection, all of these sets terminate at the proximal end with the P-Cap connector. The P-Cap connector has a stainless steel needle that punctures and penetrates the insulin cartridge, creating an aseptic fluid path to the user. The P-Cap also attaches to the pump housing creating a water tight interface between the pump housing and the P-Cap, precluding water ingress into the pump through the cartridge reservoir chamber. Once sealed onto the pump, the hydrophobic membrane in the P-Cap enables pressure equalization between the inside of the pump (external to the drug reservoir) and the external environment under all ambient pressure conditions. This venting mechanism is designed to allow equalization of a pressure differential created by an altitude change between sea level and 10,000 feet air within 10 minutes, will withstand 8 feet of water for 30 minutes, and have a dry out time of 10 minutes or less.

All of the subject sets are identical to the predicate sets in design, materials, manufacture, user interface, labeling, indications for use and intended use

Top

except for the material of the P-Cap Membrane.

7.0 Indication for Use

These sets are intended to be used with Medtronic Paradigm Insulin Subcutaneous Infusion Pumps for continuous subcutaneous insulin infusion by patients or caregivers in the home environment.

These Indications for Use have been updated to more accurately reflect that these pumps have always been intended for use with Medtronic Insulin Infusion pumps.

8.0 Intended Use

The Intended Use has not been modified.

9.0 Technological Characteristics

The overall technological characteristics of the Subcutaneous Infusion Sets have not changed. It performs all of the same functions in exactly the same manner as the predicate devices. The only change was to the material used for the gas permeable membrane that enables the pressure to equilibrate between the cartridge and the ambient environment, which was changed to ensure the flow of air is not adversely impacted when the membrane becomes wet. The use of a gas permeable membrane to enable equilibration of pressure between the cartridge and the ambient environment has always been a technological characteristic. This change of materials only ensures reliable performance is instances where the membrane become wet.

10.0 Performance and Safety Data

Three (3) different lots of POREX membrane (P/N D6014672-009) were used to produce three (3) different PQ lots of the PCAP assemblies (P/N D7004363-029). All samples were sterilized three (3) times using regular production sterilization process, then subjected to several preconditioning steps, including aging.

The following verification testing was performed to confirm proper function of the P-Cap. All samples passed the tests.

<u>Water Ingress and Dry out Time Test</u>

The P-Cap components were tested for leakage to ensure they provided an effective barrier to the transmission of moisture into the pump cartridge. They were attached to a sealed pump cartridge chamber and subjected to pressure equal to submersion in 8 feet of water for 30 minutes. Then the cartridge chamber was checked for the presence of any moisture. The wet Components were then tested to ensure that they dried out within 10 minutes.

<u>Dry and Wet Flow Test</u>

Air was passed through the membrane at a constant pressure and the flow through the membrane is measure to ensure that they enabled a minimum

Top

of 5 SCCM flow which had been determined as the minimum air flow which will allow equalization of the pressure to ambient in the cartridge chamber. The device was tested both when dry and when wet to simulate if insulin leaked into the connector during filling.

11.0 Conclusion

Unomedical A/S confirmed that the devices passed all testing and concluded that the Subcutaneous lnfusion Sets are substantially equivalent to products the predicate devices.

Top