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

September 22, 2016

Medtronic MiniMed
Noreen Bajwa
Sr. Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 91325

Re: K160860
Trade/Device Name: MiniMed Quick-serter
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: August 24, 2016
Received: August 25, 2016

Dear Noreen Bajwa:

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" (21CFR 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,

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)*

K160860

Device Name

MiniMed Quick-serter

Indications for Use *(Describe)*

The MiniMed Quick-serter is indicated to use as an aid for inserting compatible devices. It is for use by a single patient. It is not for use by multiple patients.

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 (21 CFR 807.92)

K160860

I. SUBMITTER [807.92(a)(1)]

Medtronic MiniMed, Inc.
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Northridge, CA USA 91325

Telephone: (818) 576-5224
Fax: (818) 576-6273

Contact Person: Noreen Bajwa
Email: noreen.bajwa@medtronic.com
Date Prepared: September 21, 2016

II. DEVICE [807.92(a)(2)]

Trade Name:	MiniMed Quick-serter
Common or Usual Name:	Syringe Needle Introducer
Regulation Name:	Introducer, Syringe Needle
Regulation Number:	21 CFR §880.6920
Product Code:	KZH
Regulatory Class:	II
Reviewing Product Branch:	General Hospital Devices Branch (GHDB)

III. PREDICATE DEVICE [807.92(a)(3)]

MiniMed Quick-serter (MMT-395), infusion set insertion system (K992300)

Reference Devices

- MiniMed Quick-set Infusion Set (K991759, K011071)
- MiniMed Pro-set Infusion Set (K160651)

Purpose of Submission

The scope of this 510(k) submission includes modifications to the device design and additional compatibility to MiniMed Pro-set infusion set.

IV. DEVICE DESCRIPTION [807.92(a)(4)]

The modified MiniMed Quick-serter (MMT-305) is a non-sterile, single patient, multi-use, hand held accessory product designed to be used as an insertion aid for compatible devices, including specific

infusion sets. It is used to insert the introducer needle and cannula through the skin and into the subcutaneous tissue. The MiniMed Quick-serter is intended to be used by a patient or clinician as a means to insert an infusion set with minimum discomfort and technique dependency.

The MiniMed Quick-serter consists of a plastic barrel containing a stainless steel spring and a handle. The device user places and securely seats the infusion set into the MiniMed Quick-serter. The serter is loaded and locked by pulling the handle (compressing the spring) until it clicks/locks into place. The serter is placed in contact with the insertion site and fired to release the infusion set. This is done by depressing the green side buttons to release the spring, which drives the infusion set forward and the insertion needle and cannula are inserted into the user's subcutaneous tissue. The release button on the top of the device is then pressed to ease the release of the infusion set from the serter.

Devices compatible to MiniMed Quick-serter (MMT-305) include:

- MiniMed Quick-set Infusion Set (K991759, K011071)
- MiniMed Pro-set Infusion Set (K160651)

V. INDICATIONS FOR USE [807.92(a)(5)]

The MiniMed Quick-serter is indicated to use as an aid for inserting compatible devices. It is for use by a single patient. It is not for use by multiple patients.

The Indications for Use statement for the MiniMed Quick-serter is not identical to the predicate device. However, the differences do not affect the intended use of the device, nor does it affect the safety and effectiveness of the device relative to the predicate.

The predicate MiniMed Quick-serter (MMT-395) is indicated for use with MiniMed Quick-set family of infusion sets. The subject MiniMed Quick-serter (MMT-305) is indicated for use with compatible infusion sets including both MiniMed Quick-set and MiniMed Pro-set families of infusion sets. Both the predicate and subject MiniMed Quick-serter are indicated for single patient, multi-use and have the same intended use for automatic insertion of infusion sets.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The MiniMed Quick-serter has similar technological characteristics as the predicate device.

The energy source for both the predicate (MMT-395) and subject (MMT-305) MiniMed Quick-serter devices is spring driven. The predicate and subject devices operate in an identical operational principle and there are no different questions of safety and effectiveness as the subject MiniMed Quick-serter (MMT-305) falls within the same classification regulation, has the same intended use and retains the same fundamental scientific technology of the predicate MiniMed Quick-serter (MMT-395).

A comparison of the technological characteristics of the predicate (MMT-395) and subject (MMT-305) MiniMed Quick-serter are provided below:

Description	(Predicate) MiniMed Quick-serter (MMT-395)	(Modified) MiniMed Quick-serter (MMT-305)
Classification	Class II	Identical
Product Code	KZH	Identical
Type of Use	Over the Counter	Identical
Compatibility	Maersk Medical A/S Contour infusion sets	MiniMed Quick-set Infusion Set MiniMed Pro-set Infusion Set
Condition of use	Single patient, multi-use	Identical
Energy Source	Spring Driven	Identical
Mode of action	Manual operation	Identical
Cocking Force	<5 lbf	Identical
Trigger/release Force	<7 lbf	0.67 lbf -7lbf
Diameter	1.89 inches	1.96 inches
Width of Pull Handle	1.386 inches	1.59 inches
Set release button	Set release button and pull handle are the same component	Set release button and pull handle are made distinct
Sterility	Non-sterile	Identical
Validated Cleaning Method	Manual	Identical
Service Life	3 years	Identical

VII. PERFORMANCE DATA [807.92(b)]

The following performance data were provided in support of the substantial equivalence determinations:

Biocompatibility

The biocompatibility evaluation was conducted in accordance with the FDA #G95-1 "Use of International Standard ISO-10993, "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing""* and international standard EN ISO 10993-1 "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within A Risk Management Process"* as recognized by FDA. The battery of testing included the following tests:

- Chemical Characterization (EN ISO 10993-18)
- Cytotoxicity (EN ISO 10993-5)
- Sensitization (EN ISO 10993-10)
- Skin Irritation (EN ISO 10993-10)

The MiniMed Quick-serter has been evaluated for biocompatibility and is acceptable for its intended use by Biological Evaluation.

Verification Testing

The design of MiniMed Quick-serter (MMT-305) was verified to provide objective evidence that the device retains its mechanical properties and functions with MiniMed Quick-set and MiniMed Pro-set infusion sets.

Performance testing performed to support the design modifications included:

- Cocking Force
- Trigger Force
- Visual/Functional
- Life Cycle testing
- Drop Test
- Warehouse Environment Storage
- Home Environment Storage
- Operating Temperature
- Operating Humidity
- Mechanical Vibration
- Chemical Resistance
- Reliability
- Cleaning
- Robust Cleaning Life Test
- Usability Evaluation of Quick-set and Pro-set Insertion with Quick-serter

The aforementioned tests were completed to internal standards:

- Ship Test - ASTM D4169 “Distribution Cycle 12, Assurance Level 1-Standard Practice for Performance Testing of Shipping Containers and Systems
- Cleaning studies- AAMI TIR12 “Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities. A guide for medical device manufacturers” and AAMI TIR30 “A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

Results from performance testing indicate that the product meets the established performance requirements.

VIII. CONCLUSION

Based on the 510(k) Summary and information provided herein, we conclude the subject device, MiniMed Quick-serter (MMT-305), is substantially equivalent to the predicate MiniMed Quick-serter (MMT-395).