October 18, 2018

Becton, Dickinson and Company
Meriam Youssef
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K181718
Trade/Device Name: BD FlowSmart Set/MiniMed Pro-Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, FPK
Dated: September 9, 2018
Received: September 18, 2018

Dear Meriam Youssef:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarket safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Geeta K.
Pamidimukkala -S

for 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)*

Device Name
BD FlowSmart™ Set/MiniMed™ Pro-Set™

Indications for Use *(Describe)*
The BD FlowSmart™ Set/MiniMed™ Pro-Set™ set is intended for the subcutaneous infusion of medication, including insulin, from an external infusion 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

Submitted By: Meriam Youssef
Staff Regulatory Affairs Specialist, BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6557
Fax: 201 847 5307

Date Prepared: October 18, 2018

Device Name:

Trade Name:	BD FlowSmart™ Set/MiniMed™ Pro-Set™
Common Name:	Intravascular adminstration set
Classification:	Class II device; 21 CFR 880.5440, (intravascular administration set)
Product Code:	FPA, FPK

Legally marketed predicate devices to which substantial equivalence is being claimed:
K160651: BD FlowSmart™ Set/MiniMed™ Pro-Set™

Device Description:
The subject infusion set is a single use infusion administration set intended to be used for 48-72 hours. The product is intended to interface with commercially available infusion pumps with suitable connections. The infusion set features a flexible perforated catheter perpendicular to an adhesive patch and detachable tubing. The tubing is connected on one end to the medication reservoir of an infusion pump and on the other end to the patient, attached to the skin by an adhesive base. The plastic catheter of the device contains a proprietary side-port. It is a single-use sterile device.

Indications for Use:
BD FlowSmart™ Set/MiniMed™ Pro-Set™ is intended for the subcutaneous infusion of medication, including insulin, from an external infusion pump.

There are no changes to the Indications for Use as a result of the device modifications.

Comparison with Predicate Devices:
The subject device has the same fundamental scientific technology as the predicated device. The purpose of this submission is to introduce design modifications to the catheter length and introducer needle gauge sizes, labeling and material modifications. BD has conducted bench studies confirming that the product performance is substantially equivalent to the predicate device. The table below provides a side by side comparison of the subject device compared to its predicate.

Feature	Subject: BD Infusion Set	Predicate Device: BD Infusion Set
510(k) Number	Pending	K160651
Manufacturer	BD	BD
Intended Use	Unchanged	The BD FlowSmart™/MiniMed™ Pro-Set™ infusion set is intended for the subcutaneous infusion of medication, including insulin, from an external infusion pump.
System components	Unchanged	Infusion set + tubing
Needle insertion method	Unchanged	Manual or Automatic via Quickserter (K160860)
Angle of Insertion	Unchanged	Straight 90 degrees
Insertion Needle Gauge	29G	30G
Catheter Length (mm)	6.6	6.0
Cannula Gauge	Unchanged	28G
Tubing Connection Type	Unchanged	Paradigm® and Luer Lock
Tubing Length (in)	Unchanged	24, 42
Connection Positions	Unchanged	Multiple
Replacement Frequency	Unchanged	Disposable, replaced every 72 hours
Provided Sterile	Unchanged	YES

Testing:

The subject device has the same technological characteristics as the predicate devices cleared in K160651. BD has verified the modifications of the subject device through bench performance and biocompatibility studies.

Bench performance studies included the following test methods:

Test Method	Acceptance Criteria	Results (Pass/Fail)
Introducer Needle Integrity during Manual Insertion	Equivalent to predicate device	Pass
Skin Penetration and Drag Force	Equivalent to predicate device	Pass
Introducer Needle to Needle Hub Strength	Equivalent to predicate device	Pass
Catheter to Base Attachment Strength	Testing in accordance with ISO 10555-1:1995	Pass
Tip Radial Strength	Equivalent to predicate device	Pass

The results of the bench studies successfully demonstrated the subject device has met the requirements.

Biocompatibility studies were conducted per ISO 10993-1 and included:

- Comparative chemical characterization
- Cytotoxicity evaluation

The results of the comparative chemical characterization demonstrated that there are no new compounds or compounds at higher levels in the subject device compared to the predicate device. An insulin compatibility study was performed to demonstrate insulin compatibility.

The testing demonstrates the BD FlowSmart™ Set/MiniMed™ Pro-Set™ device meet requirements for its intended use and is substantially equivalent to its predicate device.

Conclusion:
The testing performed demonstrates the BD FlowSmart™ Set/MiniMed™ Pro-Set™ device is substantially equivalent to its predicate device.