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

April 7, 2016

Becton, Dickinson And Company
Mr. Matthew Trachtenberg
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07666

Re: K160651
Trade/Device Name: BD FlowSmart™ Set/MiniMed™ Pro-Set™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: March 7, 2016
Received: March 9, 2016

Dear Mr. Trachtenberg:

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,

for Erin I. Keith, M.S.
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)*

K160651

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

Indications for Use *(Describe)*
The BD FlowSmart™/MiniMed™ Pro-Set™ infusion 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.

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

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510(k) Summary

Submitted By: Matthew S. Trachtenberg
Staff Regulatory Affairs Specialist, BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: (201) 847-6337
Fax: (201) 847-5307

Date Prepared: April 7, 2016

Device Name:

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

Legally marketed predicate devices to which substantial equivalence is being claimed:
K153257 – BD FlowSmart™ Set/MiniMed™ Pro-Set™

Device Description:
The BD FlowSmart™/MiniMed™ Pro-Set™ infusion set is a subcutaneous administration set 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. It is a single-use sterile device.

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

Comparison with Predicate Devices:
The BD FlowSmart™ Set/MiniMed™ Pro-Set™ infusion set has the same intended use as its predicate device for the subcutaneous delivery of fluids and medication, including insulin, from an external infusion pump. Additionally, the fundamental scientific technology of the proposed device is unchanged from the legally marketed device. The technological characteristics include an adhesive base, catheter, and tubing connection components. The needle insertion method, 90 degree angle of insertion, and tubing connection types are identical features to its predicate device. The modifications made include the incorporation of an alternate adhesive material. Non-clinical testing supports substantial equivalence of the subject device despite these technological differences. The table below provides a side by side comparison of the subject device compared to its predicate.

Feature	Subject Device: BD FlowSmart™ Set/ MiniMed™ Pro-Set™	Predicate Device: BD FlowSmart™ Set/ MiniMed™ Pro-Set™
510(k) Number	TBD	K153257
Manufacturer	BD	BD
Intended Use	For the subcutaneous infusion of medication, including insulin, from an external infusion pump.	For the subcutaneous infusion of medication, including insulin, from an external infusion pump.
System Components	Infusion set + tubing	Infusion set + tubing
Needle Insertion Method	Manual or Automatic	Manual or Automatic
Insertion Needle Gauge	30G	30G
Angle of Insertion	Straight 90 degrees	Straight 90 degrees
Plastic Cannula Length	6mm	6mm
Plastic Cannula Gauge	28G	28G
Tubing Connection Type	Paradigm® and Luer Lock	Paradigm® and Luer Lock
Tubing Length (cm)	61 and 107	61 and 107
Connection Positions	Multiple	Multiple
Replacement Frequency	Disposable, replaced every 72 hours	Disposable, replaced every 72 hours
Provided Sterile	YES	YES

Testing:
A risk assessment was performed and, based on the risks, BD has performed non-clinical testing to demonstrate substantial equivalence. This testing included assessments related to device material biocompatibility (ISO 10993 Parts 1, 5, and 18: Biological evaluation of medical devices), and device functional performance (ISO 10555-1: Sterile single use intravascular catheters, ISO ID26: Medical Electrical Equipment. Part 2: Particular requirements for the safety of infusion pumps, ISO 11135-1: Sterilization of healthcare products). Results of these tests were found to be acceptable and demonstrated that the subject infusion set met requirements for its intended use and is substantially equivalent to its predicate device.

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