DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2015

Becton, Dickinson Company
Ms. Avital Merl
Regulatory Affairs Manager
1 Becton Drive
Franklin Lakes, NJ 07666

Re: K150059
Trade/Device Name: BD FlowSmart™ Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: March 24, 2015
Received: March 25, 2015

Dear Ms. Merl:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 -S

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

Indications for Use Statement

510(k) Number (if known): K150059

Device Name: BD FlowSmart™ Set

Indications for Use:

The BD FlowSmart™ set is intended for the subcutaneous infusion of medication, including insulin, from an external infusion pump.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

510(k) Summary

Submitted By: Avital Merl
Regulatory Affairs Manager, BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 4739
Fax: 201 847 5307

Date Prepared: April 28, 2015

Device Name:

Trade Name:	BD FlowSmart™ 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:
K011071- Medtronic's MiniMed Quickset
K130468- Ypsomed's Orbit Infusion Set

Device Description:
The BD FlowSmart™ 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™ set is intended for the subcutaneous infusion of medication, including insulin, from an external infusion pump.

Comparison with Predicate Devices:
The BD FlowSmart™ set has a similar intended use as its predicate devices for the subcutaneous delivery of fluids and medication, including insulin, from an external infusion pump. It also shares several similarities in technology compared to its predicate devices. These 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 also similar features to its predicate devices. The technological differences include feature of a single 6mm cannula length, a 30G insertion needle and 28G plastic cannula. Pre-clinical testing and published literature support 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 predicates.

Feature	Subject Device: BD FlowSmart™ Set	Primary Predicate Device: MinMed Quick-Set	Secondary Predicate Device: Orbit Infusion Set
510(k) Number	NA	K011071	K130468
Manufacturer	BD	Medtronic	Ypsomed
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.	For the subcutaneous delivery of fluids and medication, such as insulin, from an external infusion pump.
System Components	Infusion set + tubing	Infusion set+ tubing	Infusion set + tubing
Needle insertion method	Manual or Automatic	Manual or Automatic	Manual
Insertion Needle Gauge	30G	27G	28G
Angle of Insertion	Straight 90 degrees	Straight 90 degrees	Straight 90 degrees
Plastic Cannula Length	6mm	6mm/9mm	6mm/9mm
Plastic Cannula Gauge	28G	25G	26G
Tubing Connection Type	Paradigm® and Luer Lock	Paradigm®	Luer Lock
Tubing Length (cm)	61 and 107	45, 58,81, and 109	45, 60, 75, and 105
Connection Positions	Multiple	Fixed	Multiple
Replacement frequency	Disposable, replaced every 72 hours	Disposable, replaced every 72 hours	Disposable, replaced every 72 hours
Provided Sterile	YES	YES	YES

Testing:
BD has performed non-clinical testing to demonstrate substantial equivalence. This testing includes device material biocompatibility (ISO 109993: Biological evaluation of medical devices), 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), animal testing (United States Department of Agriculture (USDA) standards, US Animal Welfare Act), and human factor evaluations (IEC 62366:2007). Results of these tests were found to be acceptable and demonstrated that the BD FlowSmart™ set met requirements for its intended use and is as safe and as effective as its predicate devices.

Conclusion:
The analysis and testing performed demonstrate the BD FlowSmart™ set is substantially equivalent to its predicate devices.