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

December 9, 2016

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

Re: K162516
Trade/Device Name: BD Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 15, 2016
Received: September 16, 2016

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. 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,

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)*
K162516

Device Name
BD Pen Needle

Indications for Use *(Describe)*
BD Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

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

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: December 7, 2016

Device Name:

Trade Name:	BD Pen Needle
Common Name:	Insulin Pen Needle
Classification:	Class II device; 21 CFR 880.5570, (hypodermic single lumen needle)
Product Code:	FMI (hypodermic single lumen needle)

Legally marketed predicate devices to which substantial equivalence is being claimed:
K051899 and K131358: BD Pen Needle
Reference Device: K110703: BD AutoShield™ Duo Pen Needle

Device Description:
The BD Pen Needle is designed for use with pen injectors for subcutaneous injection of a desired dose of drugs approved for delivery using a pen needle. It consists of a needle, hub, and shield assembly. The BD Pen Needle is offered in a variety of needle gauge sizes (29G, 30G, 31G, and 32G) and lengths (4mm, 5mm, 8mm, and 12.7mm). It is a single-use disposable device that is provided sterile. The BD Pen Needle is non-toxic and non-pyrogenic.

Intended Use:
BD Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

Comparison with Predicate Devices:
The subject device has the same device design, materials, fundamental scientific technology and device performance as the predicate devices (K051899 and K131358). The purpose of this submission is to provide clarification to the intended use which is similar amongst the cited predicate devices. The table below provides a side by side comparison of the subject device compared to its predicate.

Feature	Subject: BD Pen Needle	Predicate Device: BD Pen Needle	Reference Device: BD AutoShield™ Duo Pen Needle
510(k) Number	Pending	K051899 and K131358	K110703
Intended Use	Becton Dickinson Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.	Becton Dickinson Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin and exenatide.	For use with pen injector devices for the injection of drugs. The product has two safety shields, which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connection-end). The locked shields help reduce the occurrence of needle sticks from both ends of the needle.
Needle Gauge Size(s)	Unchanged	29G, 30G, 31G, 32G	30G and 31G
Needle Length Size(s)	Unchanged	4mm, 5mm,8mm, and 12.7mm	5mm and 8mm
Tip Geometry (Configuration)	Unchanged	3 or 5 bevel	3 bevel
Needle insertion method	Unchanged	Manual	Manual
Provided Sterile	Unchanged	YES (Gamma Irradiation)	YES (Gamma Irradiation)

Testing:

The subject device has the same technological characteristics as the predicate devices cleared in K051899 and K131358. BD has validated the design of the subject device as part of its design control process in accordance with the Quality System Regulation. This testing included functional performance per ISO 11608-2: Needle-based injection systems for medical use – Requirements and test methods– Part 2: Needles.

The clarification to the intended use of the BD pen needle device, in the Instruction for Use, does not introduce critical differences or new risks to the intended therapeutic use of the device. The proposed clarification reflects current medical practice and aligns with BD's compatibility summary displayed on the device package. BD conducts internal testing as part of its Quality System, to support the compatibility of its pen needle devices with all leading diabetes pen injectors available on the market to ensure connectivity and dose accuracy. This testing demonstrates the BD Pen Needle device meet requirements for its intended use and supports the proposed clarification.

Conclusion:
The subject device is substantially equivalent to its predicate devices.