DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 6, 2016

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

Re: K161553
Trade/Device Name: BD SafeAssist™
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 3, 2016
Received: June 6, 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 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): K161553

Device Name: BD SafeAssist™ Pen Needle

Indications for Use:

The BD SafeAssist™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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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: June 30, 2016

Device Name:

Trade Name:	BD SafeAssist™
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:
K060007: BD AutoShield™ Pen Needle

Reference device:
K110703: BD AutoShield™ Duo Pen Needle

Device Description:
The BD SafeAssist™ safety 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. The BD SafeAssist™ features a 30G needle gauge size and is offered in needle lengths of 5mm and 8mm. It is a single-use disposable device that is provided sterile (gamma irradiation sterilization). BD SafeAssist™ is non-toxic and non-pyrogenic.

The BD SafeAssist™ is designed to reduce occurrence of accidental needle sticks from the patient end of the needle by providing a shield that locks over the needle after use. Prior to injection, the user will attach the BD SafeAssist™ to the pen injector. The shield of the BD SafeAssist™ will hide the needle prior to use. As the user presses the BD SafeAssist™ against the skin at a 90° angle, the shield retracts to expose the needle and allows it to penetrate the skin. After injection is completed and the BD SafeAssist™ is removed from the skin, the shield extends automatically and locks in place to cover the needle. The locked shield is designed to reduce the occurrence of accidental needle stick injuries. The device also features a red band indicator which provides the user visual confirmation the needle's safety mechanism has been activated. The BD SafeAssist™ should be removed from the pen and discarded after use.

The BD SafeAssist™ device comprised of modifications to the BD AutoShield™ predicate cleared under K060007. These modifications consist of design, material and labeling changes.

Intended Use:
The BD SafeAssist™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

Comparison with Predicate Devices:
The BD SafeAssist™ Pen Needle has the same intended use as its predicate device. The modifications made to the device design and materials do not impact the fundamental scientific technology or performance of the device. 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 SafeAssist™	Predicate Device: BD AutoShield™ Pen Needle	Reference Device: BD AutoShield™ Duo Pen Needle
510(k) Number	Pending	K060007	K110703
Intended Use	The BD SafeAssist™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	The AutoShield™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	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)	30G	29G, 30G and 31G	30G and 31G
Needle Length Size(s)	5mm and 8mm	5mm, 8mm and 12.7mm	5mm and 8mm
Tip Geometry (Configuration)	3 bevel	3 bevel	3 bevel
Needle insertion method	Manual	Manual	Manual
Sterility Barrier	YES (peel-away label)	YES (label on cover)	YES (peel-away label)
Provided Sterile	YES (Gamma Irradiation)	YES (Gamma Irradiation)	YES (Gamma Irradiation)
Visual Indicator	Red band	Metal Clips/ Tabs	Red band
Patient end shield	Sleeve and Shield	Shield	Sleeve and Shield
Locking Element	YES (molded)	YES (metal clips)	YES (molded)
Component Material			
Outer Cover	Polyethylene (White)	Polypropylene (White)	Polyethylene (White)
Sleeve	Polycarbonate (Grey)	N/A	Polycarbonate (White)
Outer Shield	Polycarbonate (Clear)	Polypropylene (White)	Polycarbonate (Clear)
Inner Shield	Polycarbonate (Clear)	N/A	Polycarbonate (Clear)
Non-Patient Shield	Polycarbonate (Clear)	N/A	Polycarbonate (Orange)

Testing:
BD has performed non-clinical performance testing based on its risk assessment. This testing included functional performance per ISO 11608-2: Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles, sterilization per ISO 11137-2 (Sterilization of Health Care Product – Radiation Part 2: Establishing the Sterilization Dose), and material biocompatibility per ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process) for the following tests:

- Cytoxicity in Cell Culture
- Hemolysis
- Acute Systemic Toxicity
- Intracutaneous Reactivity
- Primary Dermal Irritation
- Pyrogenicity
- Sensitization
- Genotoxicity (Bacterial and Mammalian)
- Subchronic Toxicity
- Leachable Colorant
- Bacterial Endotoxin

Results of testing demonstrated the BD SafeAssist™ pen needle device met requirements for its intended use and demonstrated substantial equivalence to its predicate devices.

Conclusion:
Based on the testing conducted, the BD SafeAssist™ pen needle device is substantially equivalent to its predicate device.