December 28, 2022

Becton, Dickinson and Company
Alec Paterno
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K223286
Trade/Device Name: BD AutoShield Duo™ Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 25, 2022
Received: October 25, 2022

Dear Alec Paterno:

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 postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2022.12.28 14:45:36 -05'00'

For Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223286

Device Name
BD AutoShield Duo™ Pen Needle

Indications for Use *(Describe)*
The BD AutoShield Duo™ Pen Needle is intended for use with pen injector devices for the subcutaneous 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.

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.

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K223286 510(k) Summary

Submitted By: Alec Paterno

Senior Regulatory Affairs Specialist

Becton Dickinson and Company

1 Becton Drive

Franklin Lakes, NJ 07417

Tel: 908 670 3376

Date Prepared: December 21, 2022

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

Legally marketed predicate device to which substantial equivalence is being claimed:

K110703: BD AutoShield™ Duo Pen Needle

Purpose of Submission:

The purpose of this submission is to provide a minor administrative update to the wording of the BD AutoShield Duo™ Pen Needle intended use statement in order to align the statement with that of other marketed BD Pen Needles (cleared under K213478, K213156, and K212015). The overall intended use is the **same** as the predicate device (K110703), with the clarification, adding the word "subcutaneous", solely intended to harmonize the statement with the rest of our pen needle portfolio. **The proposed clarification has no impact on the use of the device, the user interface, technological characteristics, or overall safety and effectiveness of the subject device compared to its predicate.**

Device Description:

The BD AutoShield Duo™ Pen Needle has the **same** intended use/indications for use, technological characteristics, and principles of operation as the predicate device cleared under K110703.

The pen needle assembly consists of a double-ended cannula that is assembled onto an injection molded hub. The internal threads allow the subject device to be screwed onto a pen injector device, further enabling the non-patient end of the cannula to penetrate through the septum of the pen injector cartridge.

The patient and non-patient ends of the cannula are visible prior to attachment to the pen injector device. The BD AutoShield Duo™ Pen Needle has safety mechanisms on both the patient and non-patient ends of the needle, allowing the needle to be shielded and locked after use, which is designed to reduce the

occurrence of accidental needle-stick injuries. The BD AutoShield Duo™ Pen Needle is a single use disposable device and is provided sterile. The subject device is non-toxic and non-pyrogenic.

Intended Use:

The BD AutoShield Duo™ Pen Needle is intended for use with pen injector devices for the subcutaneous 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.

The intended use of the subject device remains the **same** as the predicate device.

Comparison with Predicate Devices:

The subject device has the same fundamental scientific technology and device performance as the predicate device (K110703). The purpose of this submission is to provide a minor update to the wording of the BD AutoShield Duo™ Pen needle intended use statement to clarify proper use of the device and align the statement with that of other marketed BD Pen Needles. The table below provides a side-by-side comparison of the subject device compared to its predicate.

Feature	Subject Device: BD AutoShield Duo™ Pen Needle	Predicate Device: BD AutoShield™ Duo Pen Needle	Comparison
510(k) Number	Pending	K110703	N/A
Product Code	FMI	FMI	Unchanged
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	Unchanged
Class	Class II	Class II	Unchanged
Intended Use	The BD AutoShield Duo™ Pen Needle is intended for use with pen injector devices for the subcutaneous 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.	The BD AutoShield Duo™ Pen Needle is intended for use with pen injector devices for the subcutaneous 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.	Unchanged, with addition of word “subcutaneous” to clarify proper injection depth
Needle Gauge	30G	30G and 31G	Unchanged
Needle Length	5mm and 8mm	5mm and 8mm	Unchanged
Pen Needle Components	Outer Cover	Outer Cover	Unchanged
	Sleeve	Sleeve	Unchanged
	Outer Shield	Outer Shield	Unchanged
	Inner Shield	Inner Shield	Unchanged
	Hub	Hub	Unchanged
	Cannula	Cannula	Unchanged
	Non-patient end Shield	Non-patient end Shield	Unchanged
	Tear Drop Label	Tear Drop Label	Unchanged
	Patient end & Non-patient end Springs	Patient end & Non-patient end Springs	Unchanged
Needle insertion method	Manual	Manual	Unchanged
Provided Sterile	Yes (gamma irradiation)	Yes (gamma irradiation)	Unchanged
Component Materials			
Outer Cover	Polyethylene	Polyethylene	Unchanged

Feature	Subject Device: BD AutoShield Duo™ Pen Needle	Predicate Device: BD AutoShield™ Duo Pen Needle	Comparison
Sleeve	Polycarbonate	Polycarbonate	Introduction of alternate resin
Outer Shield	Polycarbonate	Polycarbonate	Introduction of alternate resin
Inner Shield	Polycarbonate	Polycarbonate	Introduction of alternate resin
Hub	Polypropylene	Polypropylene	Unchanged
Cannula	Stainless Steel	Stainless Steel	Unchanged
Lubricant	Medical Grade Lubricant	Medical Grade Lubricant	Unchanged
Non-patient end Shield	Polycarbonate	Polycarbonate	Introduction of alternate resin
Tear Drop Label	Paper	Paper	Unchanged
Patient end & Non-patient end Springs	Stainless Steel	Stainless Steel	Unchanged

The differences between the predicate and subject device do not raise any new questions of safety or effectiveness.

Performance Testing:

Non-Clinical Test Summary

The subject device has the same technological characteristics as the predicate device cleared under K110703. 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 11608-2:2012, ISO 9626:2016, ISO 23908:2011, BD internal test requirements, as well as Biocompatibility testing per ISO 10993-1:2018.

Functional Performance Testing

- ISO 11608-2:2012 – Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles
- ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices – requirements and test methods
- ISO 23908:2011 – Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- BD internal test requirements

Biocompatibility Testing:

The following testing was conducted according to ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process:

- Cytotoxicity
- Intracutaneous Reactivity
- Skin Sensitization
- Acute Systemic Toxicity
- Subacute/Subchronic Toxicity
- Genotoxicity – Bacterial and Mammalian
- Material-Mediated Pyrogenicity
- Implantation

- Bacterial Endotoxin

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Shipping and Shelf-Life:

- The BD AutoShield Duo™ Pen Needle is sterilized using a validated gamma irradiation sterilization method by Cobalt-60. It has been validated via the method described in ISO 11137-2:2013 – Sterilization of Health Care Product – radiation – Part 2: Establishing the Sterilization Dose. The sterilization parameters were chosen to assure the sterilization dose provides a minimum SAL of 10^{-6}.
- Residuals are not applicable for the gamma irradiation sterilization method
- Limulus Amebocyte Lysate (LAL) assay was used to measure the endotoxin limit and the requirement was met. The product is non-pyrogenic.
- This device is packaged in an Outer Cover with a tamper evident peel-away tear drop label. The tear drop label is the sterility barrier of the medical device
    - Sterile barrier testing performed on the subject device:
        - Tear drop label removal force
        - Seal integrity
- Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for protection of product and sterility maintenance.
- Accelerated stability testing has been conducted to validate the sterility and performance of the BD AutoShield Duo™ Pen Needle device to support a shelf-life of 3 years.

Clinical Test Summary

No clinical study was included in this submission.

Conclusion:

The results of functional performance and biocompatibility testing passed and successfully demonstrated the subject device met requirements. The non-clinical testing has demonstrated the subject device is substantially equivalent to its predicate device.