July 11, 2022

Becton, Dickinson and Company
Charlton Foo
Senior Manager Regulatory Affairs
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K213478
Trade/Device Name: BD Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI

Dear Charlton Foo:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter issued June 28, 2022. Specifically, FDA is updating this SE Letter as an administrative correction to correct the device name on the Indications for Use form and include the missing date information on the original SE Letter which should have been June 28, 2022.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact CAPT Alan Stevens, by phone at 301-796-6294 or email at alan.stevens@fda.hhs.gov.

Sincerely,

Alan M. Stevens -S3

CAPT 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

Becton, Dickinson and Company
Charlton Foo
Senior Manager, Regulatory Affairs
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K213478
Trade/Device Name: BD Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 23, 2022
Received: May 25, 2022

Dear Charlton Foo:

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: 2022.06.28 10:46:16 -04'00'

For CAPT 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)*
K213478

Device Name
BD Pen Needle

Indications for Use *(Describe)*
Becton Dickinson Pen Needle is intended for use with pen injector devices for 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.

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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."

K213478.510K Summary

Submitter:

Submission Correspondent:

Charlton Foo
Senior Manager Regulatory Affairs
Tel: 857 270 1395

Applicant:

Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

Contact:

Mark O'Donnell
Vice President, Regulatory Affairs, Medical Segment
Tel: 805 452 3449

Date Prepared: June 28, 2022

Device Name:

Trade Name:	BD Pen Needle
Common Name:	BD Pen Needle
Regulation Name:	Hypodermic Single Lumen Needle
Regulation:	21 CFR 880.5570
Device Class:	Class II
Product Code:	

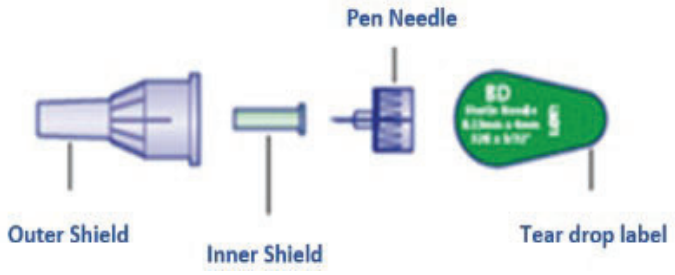
Predicate

K162516: BD Pen Needle

Device Description:

The BD Pen Needle has the **same** intended use/indications for use, technological characteristics, and principles of operation as the predicate device cleared under K162516. The pen needle assembly consists of a double-ended cannula that is assembled into an injection-molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen-injector device. This allows the Non-Patient (NP) end of the cannula to penetrate through the rubber septum of the pen injector cartridge. The Patient and NP

ends of the cannula are lubricated using silicone-based lubes for ease of injection and rubber septum penetration. An injection-molded inner shield is assembled over the Patient end of the cannula to protect the point from damage and accidental needle sticks. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away (tear drop) label to provide a sterile barrier and tamper evidence. The outer cover is also used to remove the hub and cannula from the pen. The peel-away tear-drop label is pre-printed with information, which includes the lot number and needle gauge / length. The BD Pen Needle is a single-use disposable device and is provided sterile (gamma irradiation sterilization). It is non-toxic and non-pyrogenic.



The BD Pen Needles are offered in the following sizes:

Gauge (G)	Length (mm)	Bevel	Wall Thickness
29G	12.7mm	3	Thin Wall
31G	8mm	3	Thin Wall
31G	8mm	5	Thin Wall
31G	6mm	3	Thin Wall
31G	5mm	3	Thin Wall
31G	5mm	5	Thin Wall
31G	5mm	3	Extra Thin Wall
32G	6mm	3	Thin Wall
32G	4mm	3	Thin Wall
32G	4mm	5	Thin Wall
32G	4mm	5	Extra Thin Wall

Indication for Use:

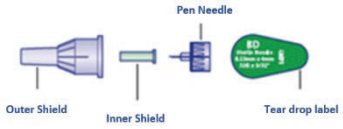
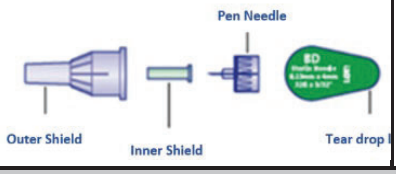
Characteristics	Predicate Device Device Name (K162516)	Subject Device Device Name (K213478)
Indication for Use	Becton Dickinson Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.	Becton Dickinson Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.
Prescription Only or Over the Counter	Over the Counter	Over the Counter

The indications for use statement for the subject device is identical to the predicate device.

Technological Characteristics

The subject device has the same fundamental scientific technology as the predicate (K162516), which operates on the principles of a single lumen needle. Compared the predicate, the subject device consists of design, performance, method, material, and labeling changes. The submission provides supporting evidence on the performance and biocompatibility of the subject device to support product changes and provide the substantiation to the most current standards and regulations. The table below provides a side-by-side comparison of the subject device compared to the predicate.

Substantial Equivalence Table

	Subject BD Pen Needles (K213478)	**Predicate BD Pen Needles (K162516)**	**Comparison**
Image			Same
General Information			
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.	Same
Device Classification	2	2	Same
Product Type	Hypodermic single lumen needle	Hypodermic single lumen needle	Same
Product Code	FMI	FMI	Same
Regulation Number	880.5570	880.5570	Same
Single Use	YES	YES	Same
Sterilization method	Gamma irradiation	Gamma irradiation	Same
SAL 10^{-6}	YES	YES	Same
Tamper Evident Feature	YES (tear-drop label)	YES (tear-drop label)	Same
Non-pyrogenic and Endotoxin Free	YES	YES	Same

Design				
	Subject BD Pen Needles		**Predicate BD Pen Needles (K162516)**	**Comparison**
Configurations	29G x 12.7mm Thin Wall 3 bevel 31G x 8mm Thin Wall 3 or 5 bevel 31G x 5mm Thin Wall 3 or 5 bevel 31G x 5mm Extra Thin Wall 3 bevel 32G x 6mm Thin Wall 3 bevel *(cleared under K182320- BD Contoured Pen Needle)* 32G x 4mm Thin Wall 3 bevel 32G x 4mm Extra Thin Wall 5 bevel **31G x 6mm Thin Wall 3 bevel** **32G x 4mm Thin Wall 3 bevel**		29G x 12.7mm Thin Wall 3 bevel 31G x 8mm Thin Wall 3 or 5 bevel 31G x 5mm Thin Wall 3 or 5 bevel 31G x 5mm Extra Thin Wall 3 bevel 32G x 6mm Thin Wall 3 bevel *(cleared under K182320- BD Contoured Pen Needle)* 32G x 4mm Thin Wall 3 bevel 32G x 4mm Extra Thin Wall 5 bevel	Different See Comment # 1
Needle Gauge Size(s)	29G, 31G, 32G		29G, 31G, 32G	Same
Cannula Length(s)	4mm, 5mm,6mm, 8mm, and 12.7mm		4mm, 5mm,8mm, and 12.7mm	Different See Comment # 2
Wall Thickness	Thin Wall or Extra Thin Wall		Thin Wall or Extra Thin Wall	Same
Needle insertion method	Manual		Manual	Same
Angle of Insertion	Straight 90 degrees		Straight 90 degrees	Same
Tip Geometry	3 or 5 bevel		3 or 5 bevel	Same
Materials				
Component	**Sub-component**	**Subject BD Pen Needles**	**Predicate BD Pen Needles (K162516)**	**Comparison**
Pen Needle	**Hub**	Polypropylene	Polypropylene	Same
	Cannula/Needle	Stainless Steel 304	Stainless Steel 304	Same
	Hub/Cannula Adhesive	UV-cured Adhesive Dymax or Loctite	UV-cured Adhesive Dymax or Loctite	Different See Comment # 3
	Lubricant (Patient End)	Medical Grade Silicone	Medical Grade Silicone	Same
	Lubricant (Non-Patient End)	Medical Grade Silicone	Medical Grade Silicone	Same
Inner Shield	**N/A**	Polyethylene with or without Colorant (**blue**, purple, **orange,** pink or green) or Polypropylene with Colorant (green)	Polyethylene with or without Colorant (blue, purple**,** pink or green) or Polypropylene with Colorant (green)	Different See Comment # 4
Outer Cover	**N/A**	Polyethylene or Polypropylene	Polyethylene or Polypropylene	Same
Tear Drop Label and Ink	**N/A**	Paper with foil layer and ink	Paper with foil layer and ink	Different See Comment # 5

Comment 1*: New configuration 31G x 6mm and 32G x 4mm 5 bevel Thin Wall was introduced to the BD pen needle family. New length was in range of previously cleared sizes under K162516. The differences between the predicate and the subject device do not raise any new questions of safety or effectiveness.*

Comment 2: *New configuration 31G x 6mm was introduced to the BD pen needle family. New length was in range of previously cleared sizes under K162516. The differences between the predicate and the subject device do not raise any new questions of safety or effectiveness.*

Comment 3: *Loctite adhesive's curing agent sourced from a new supplier. The differences between the predicate and the subject device do not raise any new questions of safety or effectiveness.*

Comment 4: *New blue colorant formulation introduced for 8mm pen needle and orange colorant for 31G x 6mm (orange colorant was cleared under K182320- BD Contoured Pen Needle and under K190054 – BD Insulin Syringe Device). The differences between the predicate and the subject device do not raise any new questions of safety or effectiveness.*

Comment 5: *A new tear-drop label ink formulation has been introduced for the BD Pen Needle. The differences between the predicate and the subject device do not raise any new questions of safety or effectiveness.*

Performance Testing

Non-clinical Testing

The subject device has the same technological characteristics as the predicate device cleared under K162516. 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, and BD internal test requirements. Material changes were evaluated in accordance with ISO 10993-1:2018: Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

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
- BD internal test requirements

Biocompatibility Testing

The device was categorized as surface medical device contacting intact skin involving prolonged contact duration for components involving direct contact with intact skin externally communicating medical device; direct contact with tissue; prolonged contact duration. 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
- Sensitization
- Intracutaneous reactivity

- Irritation
- Material Mediated Pyrogenicity
- Genotoxicity
- Implantation and Particulate Analysis
- Chemical Characterization
- Toxicological Risk Assessment

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

Sterility, Shipping and Shelf-life

- The BD 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 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

- Packaging Integrity Testing under simulated shipping conditions were conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging deemed acceptable for protection of product and sterility maintenance.

- Accelerated stability testing has been conducted to validate the sterility and performance of the BD Pen Needle device to support the shelf-life of 5 years.

Conclusion:

The modifications of the design, material and labelling to the subject device compared to the predicate device in K162516 met the requirements of the standards. The differences between the predicate (K162516) and the subject device do not raise any new or different questions of safety or effectiveness. The BD Pen Needle is substantially equivalent to the predicate BD Pen Needle (K162516).