December 23, 2021

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

Re: K182320
Trade/Device Name: BD Contoured Base Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI

Dear Meriam Youssef:

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 dated December 20, 2018. Specifically, FDA is updating this SE Letter to indicate in the Indication for Use form that the cleared device is an Over-the-Counter and not Prescription only (Rx) as previously indicated.

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

December 20, 2018

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

Re: K182320
Trade/Device Name: BD Contoured Base Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 19, 2018
Received: November 20, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah B. Mollo
-S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K182320

Device Name
BD Contoured Base Pen Needle

Indications for Use *(Describe)*
Becton Dickinson 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 K182320

Manufactures Name: Becton, Dickinson and Company

Parent Company: Becton, Dickinson and Company (BD Medical- Diabetes Care)

Corresponding Official: Meriam Youssef
Senior Manager Regulatory Affairs, BD Medical- Diabetes Care
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6557
Fax: 201 847 5307

Summary Date: December 20, 2018

Device Name:

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

Legally marketed predicate device to which substantial equivalence is being claimed:
K162516: BD Nano™ Pen Needle

Device Description:
The BD Contoured Base 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, base, and shield assembly. The BD Contoured Base Pen Needle is offered in a 32 gauge size and 4mm length. It is a single-use disposable device that is provided sterile. The BD Contoured Base Pen Needle is non-toxic and non-pyrogenic.

Indications for Use:
Becton Dickinson Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

The indications for use of the subject device remains the same as the predicate device.

Comparison with Predicate Devices:
The subject device has the same materials, fundamental scientific technology and device performance as the predicated device (K162516). The purpose of this submission is to market the BD Contoured Base Pen Needle device with the changes described in the table below. This 510(k) provides supporting evidence on the performance characteristics of the

subject device. The table below provides a side by side comparison of the subject device compared to its predicate.

Feature	Subject: BD Contoured Base Pen Needle	Predicate Device: BD Nano™ Pen Needle	Comments
510(k) Number	K182320	K162516	N/A
Indications 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.	N/A
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.	N/A
Pen Needle components	Pen needle hub (non-posted)	Pen needle hub (posted)	The subject device with modifications met the requirements per ISO 11608-2. Therefore, the modifications do not raise questions respective of safety or efficacy of the subject device.
	Inner needle shield (flat squared contour top and grips)	Inner needle shield (flat top)	
	Outer Cover (wider outer cover with flat top and longer grips)	Outer Cover (with grips)	
	Cannula (32G x 4mm extra thin wall 5 bevel)	Cannula (32G x 4mm extra thin wall 5 bevel)	
Needle insertion method	Unchanged	Manual	N/A
Product type	Unchanged	Hypodermic single lumen needle	N/A
Angle of Insertion	Unchanged	Straight 90 degrees	N/A
Tip Geometry	Unchanged	5 Bevel	N/A
Tamper Evident Feature	Unchanged	Yes (peel-away label)	N/A
Replacement Frequency	Unchanged	Disposable, single use	N/A
Provided Sterile (Method of Sterilization)	Unchanged	YES (Gamma Irradiation)	N/A
Non-pyrogenic	Unchanged	Yes, per USP<85>	N/A
Needle Gauge Size	Unchanged	32G	N/A
Needle Length size	Unchanged	4mm	N/A
Inner Diameter	Unchanged	Dimensions per ISO 9626 Table 1 Section 5	N/A
Outer Diameter	Unchanged	Dimensions per ISO 9626 Table 1 Section 5	N/A
Cannula	Unchanged	Stainless Steel	N/A
Cannula Lubricant	Unchanged	Medical Grade Lubricant	N/A
Cannula Adhesive	Unchanged	UV Cured Adhesive	N/A
Needle Hub	Unchanged	Polypropylene	N/A
Needle Shield	Unchanged	Polypropylene	N/A

Feature	Subject: BD Contoured Base Pen Needle	Predicate Device: BD Nano™ Pen Needle	Comments
Outer Shield (Outer Cover)	Unchanged Polypropylene	Polyethylene or Polypropylene	Predicate device outer cover material is either polypropylene or polyethylene; while subject device outer cover is polypropylene.
Tear drop Label	Unchanged	Paper	N/A

Testing:

Non- Clinical Test Summary:

The subject device has the same technological characteristics as the predicate device cleared in 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: Needle-based injection systems for medical use – Requirements and test methods– Part 2: Needles, and Biocompatibility testing per ISO 10993-1: Biological Evaluation of Medical Devices– Part 1: Evaluation and testing.

Functional Performance Testing included the following tests per ISO 11608-2:

- Determination of Flow Rate through needle
- Bond between hub and cannula
- Pen Installation and Removal Torque
- Dose Accuracy

Biocompatibility Testing included the following tests per ISO 10993-1:

- Chemical Characterization
- Cytotoxicity
- Intracutaneous Reactivity
- Skin Sensitization
- Acute Systemic Toxicity
- Subacute/ Subchronic Toxicity
- Genotoxicity- Bacterial and Mammalian
- Hemolysis Test
- Material Mediated Pyrogenicity
- Bacterial Endotoxin

The results of the functional performance and biocompatibility testing passed and successfully demonstrated the subject device has met the requirements.

Clinical Test Summary:

No clinical study is included in this submission.

Conclusion:

The non-clinical testing demonstrated the subject device is substantially equivalent to its predicate device.