November 19, 2021

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

Re: K212015
Trade/Device Name: BD Nano 2nd Gen Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 25, 2021
Received: October 26, 2021

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,

CAPT Alan M. 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.

Submission Number *(if known)*

Device Name

BD Nano™ 2nd Gen 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.

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510(k) Summary

Submitted By: Charlton Foo
Staff Regulatory Affairs Specialist
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6869
Fax: 201 847 5307

Date Prepared: June 23, 2021

Device Name:

Trade Name:	BD Nano™ 2nd Gen 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:
K182320: BD Contoured Base Pen Needle

Device Description:
The BD Nano™ 2nd Gen Pen Needle is designed for use with pen injectors for subcutaneous injection of a desired dose of drugs. It consists of a needle, base, and shield assembly. The BD Nano™ 2nd Gen 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 Nano™ 2nd Gen Pen Needle is non-toxic and non-pyrogenic.

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

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 predicated device (K182320). The purpose of this submission is to market the BD Nano™ 2nd Gen Pen Needle device with a proposed alternate resin material. The table below provides a side-by-side comparison of the subject device compared to its predicate.

Feature	**Subject Device: BD Nano™ 2nd Gen Pen Needle**	**Predicate Device: BD Contoured Base Pen Needle (K182320)**	**Comparison**
510(k) Number	Pending	K182320	N/A
Product Code	FMI	FMI	Unchanged
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	Unchanged
Class	II	II	Unchanged
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.	Unchanged
Needle Gauge	32G	32G	Unchanged
Needle Length	4mm	4mm	Unchanged
Pen Needle Components	Needle Hub	Needle Hub	Unchanged
	Inner Needle Shield	Inner Needle Shield	Unchanged
	Wide Outer Cover	Wide Outer Cover	Unchanged
	Cannula (32G x 4mm 5 bevel)	Cannula (32G x 4mm 5 bevel)	Unchanged
	Tear Drop Label	Tear Drop Label	Unchanged
Needle insertion method	Manual	Manual	Unchanged
Provided Sterile	YES (Gamma Irradiation)	YES (Gamma Irradiation)	Unchanged
Hub	Polypropylene	Polypropylene	Introduction of alternate polymer from a secondary supplier
Needle	Stainless Steel	Stainless Steel	Unchanged
Lubricant	Medical Grade Lubricant	Medical Grade Lubricant	Unchanged

Feature	Subject Device: BD Nano™ 2nd Gen Pen Needle	Predicate Device: BD Contoured Base Pen Needle (K182320)	Comparison
Inner Needle Shield	Polypropylene	Polypropylene	Introduction of alternate polymer from a secondary supplier
Wide Outer Cover	Polypropylene	Polypropylene	Introduction of alternate polymer from a secondary supplier
Tear Drop Label	Paper	Paper	Unchanged

The modifications to the materials were assessed through performance testing per ISO 11608-2:2012 and ISO 10993-1:2018. The differences between the predicate and subject device do not raise any new questions of safety or effectiveness.

Testing:

Non-Clinical Test Summary

The subject device has the same technological characteristics as the predicate device cleared in K182320. 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 include 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:

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

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.