December 8, 2021

Becton, Dickinson and Company
Mark William
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K213156
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: November 15, 2021
Received: November 16, 2021

Dear Mark William:

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)*

K213156

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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K213156

510(k) SUMMARY

Becton, Dickinson and Company

BD Nano™ 2nd Gen Pen Needle

Submitted By: Mark William
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 732-527-5008

Date Prepared: September 16, 2021

Device Name:

Trade Name:	BD Nano™ 2nd Gen Pen Needle
Common Name:	BD Pen Needle
Classification:	Class II device; 21 CFR 880.5570, (hypodermic single lumen needle)
Product Code:	FMI (Needle, Hypodermic, Single Lumen)

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

BD Contoured Base Pen Needle (K182320)

Reason for Submission:

The purpose of this submission is to market a new BD Pen Needle size that utilizes all the same components and processes as the currently marketed product, BD Contoured Base Pen Needle, but with a 34G cannula instead of a 32G cannula.

Device Description:

The BD 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 Nano™ 2nd Gen Pen Needle is offered in a 34-gauge size and 4mm length XTW cannula. The device is non-toxic and non-pyrogenic. It is a single-use disposable device that is provided sterile.

Intended Use / 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 its predicate device.

Comparison with Predicate Devices

The technological characteristics of the subject device are similar to those of the predicate device. A summary of the differences between BD Nano™ 2nd Gen Pen Needle subject device and BD Contoured Base Pen Needle cleared under K182320 are outlined in Table 1 below.

Table 1: Comparison of Subject and predicate devices

General Information Feature	Subject Device: BD Nano™ 2nd Gen Pen Needle	Predicate Device: BD Contoured Base Pen Needle	Comparison
510(k) Number	K213156	K182320	N/A
Device Classification	2	2	Same
Regulation Number	880.5570	880.5570	Same
Product Code	FMI (Class 2) - Needle, Hypodermic, Single Lumen	FMI (Class 2) - Needle, Hypodermic, Single Lumen	Same
Indications of 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
Single Use Only	YES	YES	Same
Non-pyrogenic	YES	YES	Same
Sterilization method	Gamma irradiation	Gamma irradiation	Same
SAL 10^{-6}	YES	YES	Same

General Information Feature	Subject Device: BD Nano™ 2nd Gen Pen Needle	Predicate Device: BD Contoured Base Pen Needle	Comparison
Cannula Gauge Size(s)	34G	32G	Different; The subject device introduces a thinner cannula with a smaller diameter; The difference has been validated with bench performance data.
Cannula Length Size(s)	4mm	4mm	Same
Cannula Tip Geometry	5 Bevel	5 Bevel	Same
Cannula Material	Stainless Steel	Stainless Steel	Same
Cannula Lubricant	Medical Grade Lubricant	Medical Grade Lubricant	Same
Cannula Adhesive	UV Cured Adhesive	UV Cured Adhesive	Same
Needle Hub Material	Polypropylene	Polypropylene	Same
Needle Shield Material	Polypropylene	Polypropylene	Same
Needle Shield Color	Green	Green	Same
Outer Shield (Cover) Material	Polypropylene	Polypropylene	Same
Tear Drop Label	Paper	Paper	Same

Non-Clinical Testing:

The subject device has similar technological characteristics as the predicate device cleared under K182320. BD 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 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles and testing following BD's Internal Specifications. The cannula component was also evaluated in accordance with ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.

Bench Functional Performance

Testing was conducted according to 11608-2:2012 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles and ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods. The evaluation performed included all testing impacted by the proposed change of introducing a 34G cannula to support the 5-year shelf life and ensure the functionality of the subject device per the intended use. The performance testing consisted of cannula straightness, cannula stiffness, cannula breakage resistance, measurement of flow rate, cannula patency, patient end penetration force, cannula pull force, and dose accuracy.

Results of testing demonstrated that the BD Nano™ 2nd Gen Pen Needle met the requirements for its intended use and is as safe and effective as its predicate device.

Clinical Test Summary

Not Applicable.

Conclusions

The modifications to the subject device met all performance testing requirements. The modifications between the predicate (K182320) and the subject devices do not raise any new or different questions of safety or effectiveness.

The BD Nano™ 2nd Gen Pen Needle is substantially equivalent to the predicate BD Contoured Base Pen Needle (K182320) with respect to the indications for use, target populations, treatment method, use environment and technological characteristics.