December 22, 2021

Becton, Dickinson and Company
Nikita Mahendra Kumar
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K210978
Trade/Device Name: BD Quincke Spinal Needle, BD Whitacre Spinal Needle, BD Spinal Introducer Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: November 18, 2021
Received: November 19, 2021

Dear Nikita Mahendra Kumar:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K210978

Device Name

BD™ Quincke Spinal Needle and BD™ Whitacre Spinal Needle

Indications for Use *(Describe)*

The BD™ Spinal Needles are intended to gain entry into or puncher the spinal cavity permitting injection (including anesthesia)/withdrawal of fluids for purposes of diagnostic lumbar puncture and myelography procedures.

This device is intended for adult and pediatric patients.

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."

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)*

Device Name
BD™ Spinal Introducer Needle

Indications for Use *(Describe)*
The BD™ Spinal Introducer Needle is intended for placement or introduction of spinal needles.

This device is intended for adult and pediatric patients.

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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510(k) Summary (21 CFR §868.5150)

BD Quincke Spinal Needle, BD Whitacre Spinal Needle and BD Spinal Introducer Needle

Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes, NJ 07417
	Contact Person:	Nikita Abirami Mahendra Kumar Senior Regulatory Affairs Specialist
	Email Address:	Nikita.Abirami.Mahendra.Kumar@bd.com
	Phone Number:	(201) 847-5641
	Date of Preparation:	November 11, 2020
Subject Device	Trade Name:	BD™ Quincke Spinal Needle BD™ Whitacre Spinal Needle BD™ Spinal Introducer Needle
	Common Name:	Anesthesia Conduction Needle
	Regulation Number:	21 CFR 868.5150
	Regulation Name:	Anesthesia Conduction Needle
	Regulatory Class:	Class II device
	Product Code:	BSP (Needle, Conduction, Anesthetic (W/Wo Introducer))
	Classification Panel:	Anesthesiology
Predicate Device	Trade Name:	BD Spinal Needle
	510(k) Reference:	K091758
	Common Name:	Spinal Needle
	Regulation Number:	21 CFR 868.5150
	Regulation Name:	Anesthesia Conduction Needle
	Regulatory Class:	Class II Device
	Product Code:	BSP (Needle, Conduction, Anesthetic (W/Wo Introducer))
	Classification Panel:	Anesthesiology
Reference Device	Trade Name:	BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle, BD® Spinal Introducer NRFit™ Needle
	510(k) Reference:	K193131
	Common Name:	Anesthesia Conduction Needle
	Regulation Number:	21 CFR 868.5150
	Regulation Name:	Anesthesia Conduction Needle
	Regulatory Class:	Class II Device
	Product Code:	BSP (Needle, Conduction, anesthetic (w/wo Introducer))
	Classification Panel:	Anesthesiology

Reason for Submission	BD received 510(k) premarket notification clearance for the 27G BD Spinal Needle with Quincke Type-point in 2009 per K091758. This 510(k) submission also includes the BD™ Whitacre Spinal Needle and the BD™ Spinal Introducer Needle. The intent of this 510(k) submission is to establish a new 510(k) baseline for these two devices.
Device Description	The BD Quincke Spinal Needle, BD Whitacre Spinal Needle are available in various gauges and needle lengths. The needle consists of a hollow needle (cannula) bonded to a clear hub at one end and a specific needle-point type (Quincke or Whitacre) at the other end. The stylet has a handle, which is color-coded and correlates to the gauge size. The BD Spinal Needle Introducer consists of a needle, needle hub and needle shield and is available in various gauges. The needle consists of a hollow needle (cannula) bonded to a translucent colored hub (per gauge) at one end and a specific needle-point type at the other end. The introducer needle is optional aid through which a spinal needle can be inserted. The BD Quincke Spinal Needle, BD Whitacre Spinal Needle and BD Spinal Needle Introducer devices are single use, sterile needles which, incorporate the ISO 594-1 and ISO 594-2 compliant connector. The needles are also available in bulk, non-sterile configurations (to be sterilized prior to use).
Indications for Use	**The BD™ Spinal Needles** are intended to gain entry into or puncture the spinal cavity permitting injection (including anesthesia) / withdrawal of fluids for purposes of diagnostic lumbar puncture and myelography procedures. These devices are intended for adult and pediatric patients. **The BD™ Spinal Introducer Needle** is intended for placement or introduction of spinal needles. This device is intended for adult and pediatric patients
Technological Characteristics	The subject devices are equivalent to the predicate devices in materials, principles of operation, design and performance characteristics. The subject devices are similar to the predicate devices in their intended use.

Element of Comparison		**Subject Devices (K210978)**	**Predicate Devices: BD Spinal Needles (K091758)**
Indications for Use		**The BD™ Quincke Spinal Needles and BD Whitacre Spinal Needles** are intended to gain entry into or puncture the spinal cavity permitting injection (including anesthesia) / withdrawal of fluids for purposes of diagnostic lumbar puncture and myelography procedures. This device is intended for adult and pediatric patients. **The BD™ Spinal Needle Introducer** is intended for placement or introduction of spinal needles. This device is intended for adult and pediatric patients.	An anesthesia conduction needle is a device used to inject local anesthetics into a patient population to provide regional anesthesia.
Needle materials	Cannula	Stainless Steel	Stainless Steel
	Hub	Polypropylene	Polypropylene
	Adhesive (Spinal Needles only)	Epoxy/Insert Molded	Epoxy/Insert Molded
Stylet materials (Spinal Needles only)	Wire	Stainless Steel	Stainless Steel
	Handle	Polypropylene + Colorant	Polypropylene
Shield Material	Shield	Polypropylene	Polypropylene
Hub Design		ISO 594	ISO 594
Sterilization Method		<u>For Sterile products:</u> Ethylene Oxide (EO)	Ethylene Oxide (EO)

SAL	10^{-6}	10^{-6}
Shelf Life	5 Years	5 Years
Needle Point	BD Quincke Spinal Needle: Quincke	BD Spinal Needle: Quincke
	BD Whitacre Spinal Needle: Whitacre	N/A
	BD Spinal Introducer Needle: Quincke	N/A
Needle Gauge	BD Quincke Spinal Needle: 18G, 20G, 22G, 23G, 25G, 26G, 27G	BD Spinal Needle: 27G
	BD Whitacre Spinal Needle: 22G, 24G, 25G, 27G	N/A
	BD Spinal Needle Introducer: 20G	N/A
Needle Length	BD Quincke Spinal Needle: 1.5" – 7"	BD Spinal Needle: 3.5", 4-11/16"
	BD Whitacre Spinal Needle: 3.5" – 5"	N/A
	BD Spinal Introducer NRFit™ Needle: 1.25"	N/A
Functional Testing:		
Fluid leakage by Pressure Decay	Per ISO 594	Per ISO 594
Subatmospheric pressure air leakage	Per ISO 594	Per ISO 594
Stress cracking	Per ISO 594	Per ISO 594
Resistance to separation from axial load	Per ISO 594	Per ISO 594
Resistance to separation from unscrewing	Per ISO 594	Per ISO 594
Resistance to overriding	Per ISO 594	Per ISO 594
Stylet Pull Force	Per internal requirements Quincke Needle	Per internal requirements Quincke Needle

	Gauge / Force (lbf) 18G ≥ 8 20G ≥ 5 22G ≥ 5 23G ≥ 5 25G ≥ 3.5 26G ≥ 3.5 27G ≥ 3.5 Whitacre Needle Gauge / Force (lbf) 22G ≥ 5 24G ≥ 5 25G ≥ 5 27G ≥ 5	Gauge / Force (lbf) 18G ≥ 8 20G ≥ 5 22G ≥ 5 23G ≥ 5 25G ≥ 3.5 26G ≥ 3.5 27G ≥ 3.5 Whitacre Needle Gauge / Force (lbf) 22G ≥ 5 24G ≥ 5 25G ≥ 5 27G ≥ 5
Handle/Hub Separation Force	Per internal requirements (Handle must not disengage when held upside down)	Per internal requirements (Handle must not disengage when held upside down)
Needle Shield/Hub Separation Force	Per internal requirements (Needle shield must not disengage from hub when held upside down)	Per internal requirements (Needle shield must not disengage from hub when held upside down)
Cannula Pull Force (Bond between hub and needle)	Per ISO 7864:2016	Per ISO 7864:2016
Biocompatibility Testing:		
Testing per ISO 10993-1:2018:		
Cytotoxicity	Per ISO 10993-5:2009, Non-cytotoxic	Per ISO 10993-5, Non-cytotoxic
Sensitization	Per ISO 10993-10:2010, Non-sensitizer	Per ISO 10993-10, Non-sensitizer
Intracutaneous Reactivity	Per ISO 10993-10:2010, Non-irritant	Per ISO 10993-10, Non-irritant
Acute Systemic Toxicity	Per ISO 10993-11:2017, Non-toxic	Per ISO 10993-11, Non-toxic
Material-Mediated Pyrogenicity	Per ISO 10993-11:2017 and USP<151>, Non-pyrogenic	Per ISO 10993-11:2017 and USP<151>, Non-pyrogenic
Chemical Characterization	Per ISO 10993-18:2005, acceptable extractables/leachables	Per ISO 10993-18:2005, acceptable extractables/leachables

	profile	profile
Additional Testing:		
Hemolysis	Per ISO 10993-4:2017, Non-hemolytic	Per ISO 10993-4, Non-hemolytic
LAL Endotoxin	Per USP<85>, 2.15 EU/device	Not specified
Particulate Matter	Per USP <788>, Met limits	Not specified
Neurotoxicity Assessment	No signs of systemic toxicity or neurological impairment from exposure of leachable compounds from the test article.	Not specified

Performance Tests

BD has performed the following non-clinical/design verification testing/analysis and the results of these tests/analysis demonstrate that the BD Quincke Spinal Needle, BD Whitacre Spinal Needle and BD Spinal Needle Introducer performed in an equivalent manner to the predicate devices.

Per ISO 594

- Fluid leakage by Pressure Decay
- Subatmospheric pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding

Per BD internal requirements:

- Stylet Pull Force
- Handle/Hub Separation Force
- Needle Shield/Hub Separation Force

Per ISO 7864:

- Cannula Pull Force (Bond between hub and needle)

BD has performed the following Material Biocompatibility Performance testing on the BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle that was cleared under K193131. The same testing is being leveraged for this submission, as the materials of the subject device are identical to that of the BD® Spinal NRFit Needles.
Per ISO 10993-1:2018:

	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material-Mediated Pyrogenicity • Chemical Characterization Additionally, the following tests were performed: • Hemolysis • LAL Endotoxin • Particulate Matter • Neurotoxicity Assessment The subject device continue to meet all the predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate device.
Clinical Testing	Clinical testing was not required for this submission
Summary of Substantial Equivalence	The BD™ Quincke Spinal Needle, BD™ Whitacre Spinal Needle and BD™ Spinal Introducer Needle are equivalent to the predicate devices in materials, principles of operation, design and performance characteristics. The subject devices are similar to the predicate devices in their intended use.