September 29, 2020

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

Re: K193131
Trade/Device Name: BD Quincke Spinal NRFit Needle, BD Whitacre Spinal NRFit Needle, BD Spinal Introducer NRFit Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: September 1, 2020
Received: September 2, 2020

Dear Murtaza Rana:

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 ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193131

Device Name
BD® Spinal Introducer NRFit™ Needle

Indications for Use *(Describe)*
The BD® Spinal Introducer NRFit™ 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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193131

Device Name
BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle

Indications for Use *(Describe)*
The BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle 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.

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 §807.92)

BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle

Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes, NJ 07417
	Contact Person:	Murtaza Rana Staff Regulatory Affairs Specialist
	Email Address:	Murtaza.rana@bd.com
	Phone Number:	(201) 847-6980
	Fax Number:	(201) 847-5307
	Date of Preparation:	September 22, 2020
Subject Device	Trade Name:	BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle, BD® Spinal Introducer NRFit™ 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:	SPROTTE® NRFit™ and Quincke NRFit™ Lumbar Puncture needles
	510(k) Reference:	K160294
	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	The purpose of this submission is to introduce an array of spinal and spinal introducer needles which comply with the ISO 80369-6:2016 standard entitled *Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*. The connectors specified in ISO 80369-6 are referred to as NRFit™ connectors. The BD spinal and spinal introducer needles with NRFit™ connectors will be referred to as BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle.	

Device Description	The BD® Quincke Spinal NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle are single use, sterile needles which incorporate an ISO 80369-6 compliant connector. The needles are also available in bulk, non-sterile configurations (to be sterilized prior to use). Each type of needle consists of a hollow, stainless steel cannula, a translucent, polypropylene hub and a polypropylene shield. The cannula is bonded to the hub at one end and there is a specific needle point (Quincke or Whitacre) at the other end. The BD® Spinal Introducer NRFit™ Needle is only available with a Quincke needle point. The BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle also contain a stylet and are available in various needle lengths. The stylet consists of a solid, stainless steel wire bonded to a polypropylene handle. All three needles are available in various gauges. The needle hubs for all three needles are ISO 80369-6 compliant connectors. The needle shields are yellow to indicate that the device is intended to only connect to ISO 80369-6 compatible devices. The stylet handle for the BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle and the needle hub of the BD® Spinal Introducer NRFit™ Needles are color coded and correlate to the gauge size per ISO 6009:2016.
Indications for Use	The BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle 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 NRFit™ Needle is intended for placement or introduction of spinal needles. This device is intended for adult and pediatric patients.

Technological Characteristics

Element of Comparison		Subject Device	Predicate Device
Indications for Use		The BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle 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 NRFit™ Needle is intended for placement or introduction of spinal needles. This device is intended for adult and pediatric patients.	The SPROTTE® NRFit™, Quincke NRFit™ lumbar puncture 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, myelography/ discography procedures. The device is intended for adult and pediatric patients.
Needle materials	Cannula	Stainless Steel	Stainless Steel
	Hub	Polypropylene or Polypropylene + Colorant (Introducer Needle only)	Polycarbonate
	Adhesive	N/A	Epoxy resin
Stylet materials	Wire	Stainless Steel	Stainless Steel
	Handle	Polypropylene +	Polycarbonate

(Spinal Needles only)		Colorant	
Shield Material	Shield	Polypropylene + Colorant	Not specified
Hub Design		Female ISO 80369-6 connector	Female ISO 80369-6 connector
Sterilization Method		For Sterile products: Ethylene Oxide (EO). Validated according to Overkill approach per ISO 11135-1:2014/Amd. 1:2018	For Sterile products: Ethylene Oxide (EO). Validated according to Overkill approach per ISO 11135-1 (version not specified)
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years
Needle Point		BD® Quincke Spinal NRFit™ Needle: Quincke	Quincke NRFit Lumbar Puncture Needles: Quincke
		BD® Whitacre Spinal NRFit™ Needle: Whitacre	SPROTTE NRFit Lumbar Puncture Needles: Sprotte
		BD® Spinal Introducer NRFit™ Needle: Quincke	Introducer Needles: Not specified
Needle Gauge		BD® Quincke Spinal NRFit™ Needle: 18G – 27G	Quincke NRFit Lumbar Puncture Needles: 20G – 27G
		BD® Whitacre Spinal NRFit™ Needle: 22G – 27G	SPROTTE NRFit Lumbar Puncture Needles: 18G – 29G
		BD® Spinal Introducer NRFit™ Needle: 18G – 20G	Introducer Needles: Not specified
Needle Length		BD® Quincke Spinal NRFit™ Needle: 1.5” – 7”	Quincke NRFit Lumbar Puncture Needles: 50mm – 120mm (1.97” – 4.72”)

	BD® Whitacre Spinal NRFit™ Needle: 3.5" – 5"	SPROTTE NRFit Lumbar Puncture Needles: 50mm – 150mm (1.97" – 5.91")
	BD® Spinal Introducer NRFit™ Needle: 1.25"	Introducer Needles: Not specified
Functional Testing:		
Fluid leakage by Pressure Decay	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Subatmospheric pressure air leakage	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Stress cracking	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Resistance to separation from axial load	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Resistance to separation from unscrewing	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Resistance to overriding	Per ISO 80369-6:2016	Per ISO 80369-6:2016
Stylet Pull Force	Per internal requirements	Not specified
Handle/Hub Separation Force	Per internal requirements	Not specified
Needle Shield/Hub Separation Force	Per internal requirements	Not specified
Cannula Pull Force (Bond between hub and needle)	Per ISO 7864:2016	Per ISO 7864:2016
Cannula Deflection/Stiffness	ISO 9626:2001	ISO 9626:2016
Cannula Breakage	ISO 9626:2001	ISO 9626:2016
Biocompatibility Testing:		
Testing per ISO 10993-1:2018:		
Cytotoxicity	Per ISO 10993-5:2009, Non-	Per ISO 10993-5, Non-cytotoxic

	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	Not specified
Chemical Characterization	Per ISO 10993-18:2005, acceptable extractables/leachables profile	Not specified
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

The indications for use for the subject BD® Quincke Spinal NRFit™ Needle and BD® Whitacre Spinal NRFit™ Needle are the same as that of the predicate devices, with the exception of additional discography use which is included for the predicate device. This difference does not impact the determination of substantial equivalence as the subject device's indications for use still fall within in the indications for use for the predicate device.

The indications for use for the subject BD® Spinal Introducer NRFit™ Needle has been specified above as intended for placement or introduction of spinal needles. While the predicate device does not specify this specific indications for use, the usage spinal needles as an introducer is a well-established clinical practice, and is typically associated with the needle gauge size. Both the subject and predicate device are available in the same size ranges. Furthermore, the introducer is still being used to enter the spinal cavity utilizing a mode of action that is identical to the predicate device. As such, all

performance testing conducted for these products remained the same. Given this, the difference does not impact the determination of substantial equivalence since the BD® Spinal Introducer NRFit™ Needle.

The differences in some of the component materials mentioned above do not impact the determination of substantial equivalence since biocompatibility testing was conducted on the entire device and individual components as applicable per ISO 10993-1:2018.

The differences in some of the technological characteristics mentioned above do not impact the determination of substantial equivalence since the same performance tests were conducted as the predicate device.

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 NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle performed in an equivalent manner to the predicate device. Per ISO 80369-6: • 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) Per ISO 9626: • Cannula Deflection/Stiffness • Cannula Breakage A biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2018. Based on the evaluation, the following biological tests were conducted: • 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 met all 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 NRFit™ Needle, BD® Whitacre Spinal NRFit™ Needle and BD® Spinal Introducer NRFit™ Needle are substantially equivalent to the predicate devices in intended use, principles of operation, technology, design, materials and performance.