July 1, 2022

Becton, Dickinson and Company
Murtaza Rana
Sr. Manager, Regulatory Affairs
1 Becton Drive
Mc 237
Franklin Lakes, New Jersey 07417

Re: K211085
Trade/Device Name: BD Perisafe Tuohy Epidural Needle, BD Perisafe Weiss Epidural Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 27, 2022
Received: May 31, 2022

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 and Part 809); 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)*
K211085

Device Name
BD Perisafe™ Tuohy Epidural Needle
BD Perisafe™ Weiss Epidural Needle

Indications for Use *(Describe)*
BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle are indicated for the administration of anesthesia or analgesia into the epidural space, or to introduce a dedicated catheter for continuous administration of anesthesia or analgesia into the epidural space. They can also be used to introduce a spinal needle to perform a combined spinal and epidural procedure.
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 Perisafe™ Tuohy Epidural Needle
BD Perisafe™ Weiss Epidural Needle

Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes, NJ 07417
	Contact Person:	Murtaza Rana Senior Regulatory Affairs Manager
	Email Address:	murtaza.rana@bd.com
	Phone Number:	(201) 847-6980
	Date of Preparation:	May 27, 2022
Subject Device	Trade Name:	BD Perisafe™ Tuohy Epidural Needle BD Perisafe™ Weiss Epidural Needle
	Common Name:	Anesthesia Epidural 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:	Epidural Anesthesia Needles, Spinal Anesthesia Needles, Combined Anesthesia Needles
	510(k) Reference:	K171518
	Common Name:	Epidural Anesthesia Needles, Spinal Anesthesia Needles, Combined Anesthesia Needles
	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 intent of this 510(k) submission is to establish a new 510(k) baseline for the BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle.	
Device Description	BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle are single use, sterile needles which incorporate an ISO 594-1/-2 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 over the needle. The cannula is bonded to the hub at one end. The BD Perisafe™ Epidural needles also contain a plastic stylet handle and are available in various needle lengths. The needle hubs are ISO 594-1 and ISO 594-2 compliant connectors. The stylet handle for the BD Perisafe™ Epidural needles is color coded and correlate to the gauge size per ISO 6009:2016.
Indications for Use	The BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle are indicated for the administration of anesthesia or analgesia into the epidural space, or to introduce a dedicated catheter for continuous administration of anesthesia or analgesia into the epidural space. They can also be used to introduce a spinal needle to perform a combined spinal and epidural procedure. These devices are intended for adult and pediatric patients.
Technological Characteristics	The subject devices are equivalent to the predicate devices in intended use, materials and performance characteristics.

Element of Comparison	Subject Device (BD Perisafe™ Tuohy Epidural Needle BD Perisafe™ Weiss Epidural Needle)	Predicate Device (Epidural Anesthesia Needles, Zhejiang kindly Medical Devices, K171518)	Substantial Equivalence
Indications for Use	The BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle are indicated for the administration of anesthesia or analgesia into the epidural space, or to introduce a dedicated catheter for continuous administration of anesthesia or analgesia into the epidural space. They can also be used to introduce a spinal needle to perform a combined spinal and epidural procedure. These devices are intended for adult and pediatric patients.	The Epidural Anesthesia Needles are intended to be used for injection into the epidural space/or placing the epidural catheter into the epidural space. The Combined Anesthesia Needles are intended for injection of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The administration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space.	Substantially equivalent to predicate device as both are intended for administration of anesthesia in epidural space and for combined spinal and epidural procedures.

Technological Characteristics			
Components	Stylet Handle Stylet Needle Tube (Cannula) Needle Hub Protective Cap of Needle (Shield)	Stylet Hub Stylet Needle Tube Needle Hub Needle Hub Insert Protective Cap of Needle	Substantially equivalent. The only difference is the absence of a needle hub insert. This is because the needle tube (cannula) is insert molded to the needle hub for the subject device.
Needle Gauge	16G – 20G	14G – 22G	The proposed devices have different combination of needle gauge and needle length compared with the predicate device. However, the different device configurations will be selected by the physician per patient's condition. Therefore, this difference is not considered to affect substantial equivalence.
Needle Length	50.8mm, 80mm, 88.9mm, 127mm	65mm, 70mm, 80mm, 90mm, 100mm, 110mm, 120mm, 150mm	
Needle Tip	Tuohy, Weiss	Tuohy	The Weiss needle tip geometry is same as the Tuohy needle tip geometry with the only difference being the addition of "wings" to the needle hub to make it easier to grasp the needle with both hands for placement. This difference is not considered to affect substantial equivalence.
Sterile	EO Sterilized, 10^{-6}	EO Sterilzed, 10^{-6}	Substantially equivalent.
Single Use	Single Use	Single Use	Substantially equivalent.
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Substantially equivalent.

Functional Testing:			
Fluid leakage by Pressure Decay	Per ISO 594-1 and 594-2	Per ISO 594-1 and 594-2	Substantially equivalent.
Subatmospheric pressure air leakage	Per ISO 594-1 and 594-2	Per ISO 594-1 and 594-2	Substantially equivalent.
Stress cracking	Per ISO 594-1 and 594-2	Per ISO 594-1 and 594-2	Substantially equivalent.
Resistance to separation from axial load	Per ISO 594-1 and 594-2	Per ISO 594-1 and 594-2	Substantially equivalent.
Resistance to separation from unscrewing	Per ISO 594-2	Per ISO 594-2	Substantially equivalent.
Resistance to overriding	Per ISO 594-2	Per ISO 594-2	Substantially equivalent.
Stylet Pull Force	Per internal requirements (Must exhibit material	Not specified	Substantially equivalent*

	stretch with no separation at stylet/handle junction)		
Handle/Hub Separation Force	Per internal requirements (Handle must not disengage when held upside down)	Not specified	Substantially equivalent*
Needle Shield/Hub Separation Force	Per internal requirements (Needle shield must not disengage from hub when held upside down)	Not specified	Substantially equivalent*
Cannula Pull Force (Bond between hub and needle)	Per ISO 7864:2016	Per ISO 7864:2016	Substantially equivalent.
Cannula deflection/ Stiffness	Per ISO 9626:2001	Per ISO 9626:1991	Substantially equivalent.
Cannula breakage	Per ISO 9626:2001	Per ISO 9626:1991	Substantially equivalent.
Biocompatibility Testing:			
Testing per ISO 10993-1:2018:			
Cytotoxicity	Per ISO 10993-5:2009, Non-cytotoxic	Per ISO 10993-5, Non-cytotoxic	Substantially equivalent.
Sensitization	Per ISO 10993-10:2010, Non-sensitizer	Per ISO 10993-10, Non-sensitizer	Substantially equivalent.
Intracutaneous Reactivity	Per ISO 10993-10:2010, Non-irritant	Per ISO 10993-10, Non-irritant	Substantially equivalent.
Acute Systemic Toxicity	Per ISO 10993-11:2017, Non-toxic	Per ISO 10993-11, Non-toxic	Substantially equivalent.
Material-Mediated Pyrogenicity	Per ISO 10993-11:2017 and USP<151>, Non-pyrogenic	Not specified	N/A
Chemical Characterization	Per ISO 10993-18:2005, acceptable extractables/leachables profile	Not specified	N/A

Additional Testing:

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

***** Although it is not clear if these tests were performed by the predicate device manufacturer and since there are differences in design and materials between the predicate and subject devices, BD performs additional testing as needed to address any potential risks identified. These internal tests help mitigate the following risks:

- Stylet Pull Force - This test addresses the risk of the stylet wire potentially separating from the stylet handle, resulting in user inconvenience and/or inability to use the product.

- Handle/Hub Separation Force - This test addresses the potential of the stylet falling out from the needle hub, which can result in user inconvenience and/or inability to use the product.

- Needle Shield / Hub Separation Force - This test addresses the potential of the shield coming off too easily from the needle hub which could result in user inconvenience or potential for needle-stick injury.

Therefore, BD believes that these additional tests are required to support the safety and effectiveness of the subject devices.

Performance Tests	BD has performed the following non-clinical/design verification testing/analysis and the results of these tests/analysis demonstrate that the BD Perisafe™ Epidural Needles 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 • Stylet Pull Force Per ISO 9626 • Cannula deflection/ Stiffness • Cannula breakage 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 Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle.

	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 BD has performed the following Material Biocompatibility Performance testing on the BD® Whitacre Spinal NRFit™ Needle that was cleared under K193131. The same testing is being leveraged for this submission, as the materials of the subject device are the same as that of the BD® Spinal NRFit Needles. • Neurotoxicity Assessment The subject device continues 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	BD Perisafe™ Tuohy Epidural Needle and BD Perisafe™ Weiss Epidural Needle are substantially equivalent to the predicate devices in its intended use, principles of operation, technology, design, materials and performance.