September 4, 2020

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

Re: K192538
Trade/Device Name: BD Syringe NRFit Lok and BD Syringe NRFit Slip
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: August 6, 2020
Received: August 7, 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,

For CAPT Alan 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.

510(k) Number *(if known)*
K192538

Device Name
BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip

Indications for Use *(Describe)*
The BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are intended for neuraxial use by healthcare professionals for aspiration/injection of fluids.

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® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Fax Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Murtaza Rana Staff Regulatory Affairs Specialist Murtaza.rana@bd.com (201) 847-6980 (201) 847-5307 August 6, 2020
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip Piston Syringe 21 CFR §880.5860 Piston Syringe Class II device QEH (Piston Syringe With Neuraxial Connector – Epidural, Peripheral and/or indirect CSF contact) General Hospital
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Single Use, Hypodermic Syringe K980987 Piston Syringe 21 CFR §880.5860 Piston Syringe Class II device FMF (Syringe, Piston) General Hospital
Reason for Submission	The purpose of this submission is to modify the tip of the current BD Single Use, Hypodermic Syringe (previously cleared under K980987) from the current Luer connections per ISO 594-1 and ISO 594-2 to the new ISO 80369-6 connectors referred to as NRFit™. The new BD syringes with NRFit™ connectors will be referred to as BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip. BD will continue to market the current BD Single Use, Hypodermic Syringes with Luer connections for general purpose use, while the new BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip will be for neuraxial use per ISO 80369-6.	
Device Description	The BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are sterile, single use syringes with ISO 80369-6 (NRFit™)	

	compliant fittings. They are available in 3mL, 5mL and 10mL, lock and slip configurations and 20mL and 50mL lock configurations. The NRFit™ tips allow for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe assembly consists of a lubricated polypropylene barrel with a graduated scale in milliliters (mL), a lubricated synthetic rubber stopper and a polypropylene plunger rod. The plunger rod is yellow to designate a device intended to only connect to ISO 80369-6 compatible devices such as spinal or epidural needles. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids.
Indications for Use	The BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are intended for neuraxial use by healthcare professionals for aspiration/injection of fluids.
Technological Characteristics	The subject BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are equivalent to that of the predicate BD Single Use, Hypodermic Syringe in intended use, materials and performance characteristics.

Element of Comparison		**Subject Device**	**Predicate Device**
Indications for Use		The BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are intended for neuraxial use by healthcare professionals for aspiration/injection of fluids.	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.
Syringe materials	Barrel	Polypropylene	Polypropylene
	Barrel Lubricant	Silicone	Silicone
	Plunger Rod	Polypropylene with yellow colorant	Polypropylene
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber
	Stopper Lubricant	Silicone	Silicone
Tip type		NRFit™ lock or slip per ISO 80369-6:2016	Luer-Lok™ or Luer Slip per ISO 594-1: 1986 and ISO 594-2:1998
Sterilization Method		Gamma Irradiation/ E-beam Irradiation	Gamma Irradiation/ E-beam Irradiation
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years
Functional Testing:			

<table>
<tr><td>Fluid leakage by Pressure Decay</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-1:1986 and ISO 594-2:1998</td></tr>
<tr><td>Subatmospheric pressure air leakage</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-1:1986 and ISO 594-2:1998</td></tr>
<tr><td>Stress cracking</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-1:1986 and ISO 594-2:1998</td></tr>
<tr><td>Resistance to separation from axial load</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-1:1986 and ISO 594-2:1998</td></tr>
<tr><td>Resistance to separation from unscrewing</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-2:1998</td></tr>
<tr><td>Resistance to overriding</td><td>Per ISO 80369-6:2016 and ISO 80369-20:2015</td><td>Per ISO 594-2:1998</td></tr>
<tr><td>Needle hub connectivity</td><td>Per BD internal requirements</td><td>Per BD internal requirements</td></tr>
<tr><td>Tip integrity</td><td>Per BD internal requirements</td><td>Per BD internal requirements</td></tr>
<tr><td>Dead space</td><td>Per ISO 7886-1:2017</td><td>Per ISO 7886-1:1993</td></tr>
<tr><td>Volumetric accuracy</td><td>Per ISO 7886-1:2017</td><td>Per ISO 7886-1:1993</td></tr>
<tr><td>Maximum usable capacity</td><td>Per ISO 7886-1:2017</td><td>Per ISO 7886-1:1993</td></tr>
<tr><td>Plunger Retention Force *</td><td>Per ISO 7886-1:2017</td><td>Per ISO 7886-1:2017</td></tr>
<tr><td>Sticktion*</td><td>Per ISO 7886-2:1996</td><td>Per ISO 7886-2:1996</td></tr>
<tr><td>Plunger Movement Force</td><td>Per ISO 7886-2:2020</td><td>N/A. Not required previously for predicate device.</td></tr>
<tr><td>Syringe Compliance</td><td>Per ISO 7886-2:2020</td><td>N/A. Not required previously for predicate device.</td></tr>
<tr><td>Break Out Force</td><td><table><tr><td>Size</td><td>Max (lb) @ 500mm/min</td></tr><tr><td>3ml</td><td>≤ 4</td></tr><tr><td>5ml</td><td>≤ 4</td></tr><tr><td>10ml</td><td>≤ 4.5</td></tr><tr><td>20ml</td><td>≤ 7.5</td></tr><tr><td>50ml</td><td>≤ 9.0</td></tr></table></td><td><table><tr><td>Size</td><td>Max (lb) @ 500mm/min</td></tr><tr><td>3ml</td><td>≤ 4</td></tr><tr><td>5ml</td><td>≤ 4</td></tr><tr><td>10ml</td><td>≤ 4.5</td></tr><tr><td>20ml</td><td>≤ 7.5</td></tr><tr><td>50ml</td><td>≤ 9.0</td></tr></table></td></tr>
<tr><td>Sustaining force</td><td><table><tr><td>Size</td><td>Max (lb) @ 500mm/min</td></tr><tr><td>3ml</td><td>≤ 1.5</td></tr><tr><td>5ml</td><td>≤ 2.0</td></tr><tr><td>10ml</td><td>≤ 2.0</td></tr><tr><td>20ml</td><td>≤ 2.5</td></tr><tr><td>50ml</td><td>≤ 5.0</td></tr></table></td><td><table><tr><td>Size</td><td>Max (lb) @ 500mm/min</td></tr><tr><td>3ml</td><td>≤ 1.5</td></tr><tr><td>5ml</td><td>≤ 2.0</td></tr><tr><td>10ml</td><td>≤ 2.0</td></tr><tr><td>20ml</td><td>≤ 2.5</td></tr><tr><td>50ml</td><td>≤ 5.0</td></tr></table></td></tr>
<tr><td>Scale Permanency</td><td>No Heavy Removal under solvent rub</td><td>No Heavy Removal under solvent rub</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Packaging Testing</td></tr>
<tr><td>Bubble Leak Testing*</td><td>Per ASTM F2096:2011</td><td>Per ASTM F2096:2011</td></tr>
<tr><td>Seal Strength</td><td>Per ASTM F88/F88M:2015</td><td>Per ASTM F88/F88M:2015</td></tr>
</table>

Testing*		
Microbial Barrier Testing*	Per ASTM F1608:2009	Per ASTM F1608:2009
Biocompatibility Testing:		
Testing per ISO 10993-1:2018:		
Cytotoxicity	Per ISO 10993-5:2009, Non-cytotoxic	Per ISO 10993-5:2009, Non-cytotoxic
Hemolysis	Per ISO 10993-4:2017, Non-hemolytic	Per ISO 10993-4:2002/ A1:2006, Non-hemolytic
Acute Systemic Toxicity	Per ISO 10993-11:2006, Non-toxic	Per ISO 10993-11:2006, Non-toxic
Intracutaneous Reactivity	Per ISO 10993-10:2010, Non-irritant	Per ISO 10993-10:2010, Non-irritant
Sensitization	Per ISO 10993-10:2010, Non-sensitizer	Per ISO 10993-10:2010, Non-sensitizer
Material-mediated Pyrogenicity	Per ISO 10993-11:2006 and USP<151>, Non-pyrogenic	Per ISO 10993-11:2006 and USP 151, Non-pyrogenic
LAL Endotoxin	Per USP<85>, 2.15 EU/device	Per USP<85>, < 0.2 EU/device
Chemical Characterization	Per ISO 10993-18:2005, acceptable extractables/leachables profile	Per ISO 10993-18:2005, acceptable extractables/leachables profile
Subacute/Subchronic	Per ISO 10993-11; No treatment related adverse effects	N/A. Not Required previously for predicate device
Genotoxicity	Per ISO 10993-3:2014, Non-mutagentic and non-clastogenic	N/A. Not required previously for predicate device.
Additional Testing :		
Acidity/Alkalinity and Extractable Metals	Per ISO 7886-1:2017, Met limits	Per ISO 7886-1:1993, Met limits
Particulate Matter	Per USP <788>, Met limits	N/A. Not required previously for predicate device.
Neurotoxicity Assessment	No signs of systemic toxicity or neurological impairment from exposure of leachable compounds from the test article.	N/A. Not required previously for predicate device.

The intended uses of the subject and predicate devices are the same in that both are intended for use by healthcare professionals for aspiration/injection of fluids. However, due to the ISO 80369-6 connector, the BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are limited to neuraxial applications. As such, the neuraxial indication, is a subset of the predicate indications for use, which is for general purpose. Therefore, the above difference in indications for use is not critical to the intended use as the intended

use remains the same: for use by healthcare professionals for aspiration/injection of fluids. It further does not affect the safety and effectiveness of the device when used as labeled as demonstrated through functional testing. Biocompatibility testing per ISO 10993 and ISO 80369 testing were conducted to address the changes in indications for neuraxial use and tip design, respectively.

Performance Tests	BD has performed the following non-clinical/design verification testing/analysis and the results of these tests/analysis demonstrate that the BD® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip performed in an equivalent manner to the predicate device. Per ISO 80369-6 and ISO 80369-20: • 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: • Needle hub connectivity • Tip integrity Per ISO 7886-1: • Dead space • Volumetric accuracy • Maximum usable capacity Per ISO 7886-2:2020: • Plunger Movement Force • Syringe Compliance A biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2018. The contact classification is external communicating, indirect contact with blood and tissue with a prolonged use. Based on the evaluation, the following biological tests were conducted: • Cytotoxicity • Hemolysis • Acute Systemic Toxicity • Intracutaneous Reactivity • Sensitization • Subacute/Subchronic

	• Genotoxicity • Material-mediated Pyrogenicity • LAL Endotoxin • Chemical Characterization Additionally, the following tests were performed: • Acidity/Alkalinity and Extractable Metals per ISO 7886-1:2017 • Particulate Matter per USP <788> • Neurotoxicity Assessment <u>Functional:</u> Per ISO 7886-1:2017: • Plunger Retention Force Per ISO 7886-2:1996: • Sticktion Per BD internal requirements: • Break Out Force • Sustaining force • Scale Permanency <u>Packaging:</u> Per ASTM F2096:2011 • Bubble Leak Testing Per ASTM F88/F88M:2015 • Seal Strength Testing Per ASTM F1608:2009 • Microbial Barrier Testing 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® Syringe NRFit™ Lok and BD® Syringe NRFit™ Slip are substantially equivalent to the predicate device in intended use, principles of operation, technology, design, materials and performance.