Carefusion
Breanna Casados
Staff Regulatory Affairs Specialist
10020 Pacific Mesa Blvd
San Diego, California 92121

Re: K231888
Trade/Device Name: BD Texium™ Needle-Free Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Syringe, Piston
Regulatory Class: Class II
Product Code: FMF, ONB
Dated: June 26, 2023
Received: June 27, 2023

Dear Breanna Casados:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.09.25 19:13:06 -04'00'

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)*
K231888

Device Name
BD Texium™ Needle-Free Syringe

Indications for Use *(Describe)*
The BD Texium™ Needle-Free Syringe is a sterile, single-use closed system drug transfer device (CSTD) incorporating a bonded Texium™ Closed Male Luer and Syringe, intended for preparation and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-free Connector (NFC). When paired with devices containing a SmartSite™ NFC the BD Texium™ Needle-Free Syringe mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the BD Texium™ Needle-Free Syringe/ SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills. (e.g., airtight, leak-free and drip-free).

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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K231888 – 510(k) Summary

Submitter Information

Company Name:	CareFusion
Company Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121, USA
Name of contact Person:	Breanna Casados, Staff Regulatory Affairs Specialist
Company Phone:	(801) 857-7561
Email:	Breanna.Casados@bd.com
Date Prepared:	September 25, 2023

Subject Device Identification

Trade/Proprietary Name:	BD Texium™ Needle-Free Syringe
Common Name:	Piston Syringe
Classification Name:	Syringe, Piston
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston Syringe
Regulatory Class:	Class II
Product Code:	FMF, ONB
Classification Panel:	General Hospital

Primary Predicate Device Identification

Trade/Proprietary Name:	Texium™ Syringe
Common Name:	Piston Syringe
Classification Name:	Syringe, Piston
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston Syringe
Regulatory Class:	Class II
Product Code:	FMF
Classification Panel:	General Hospital
Premarket Notification:	K071108

Secondary Predicate Device Identification

Trade/Proprietary Name:	BD Texium™ Closed Male Luer
Common Name:	Closed System Drug Transfer Device (CSTD)
Classification Name:	Closed Antineoplastic and Drug Reconstitution and Transfer System
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular Administration Set
Regulatory Class:	Class II

Product Code: ONB
Classification Panel: General Hospital
Premarket Notification: K223076

Reason for the Submission

The reason for this submission is to incorporate the following changes:

- Including the recently cleared BD Texium™ Closed Male Luer (K223076)
- Updating Indications for Use to align with ONB product code
- Fluid path sterile claim to content sterile

Device Description

The BD Texium™ Needle-Free Syringe is a single use piston syringe that consists of a syringe (3mL, 5mL, 10mL, 20mL, 30mL, or 50mL) permanently bonded to a closed male luer device (BD Texium™ Closed Male Luer, K223076). The Texium™ Syringe is designed to promote safe handling of fluids and medications, particularly hazardous or cytotoxic drugs. Leakage of drug into the environment is effectively avoided during all phases of drug handling when the BD Texium™ Needle-Free Syringe is used in conjunction with the SmartSite™ Needle-Free Connector: the preparation of the drug, the administration of the drug to the patient, and waste handling. The BD Texium™ Needle-Free Syringe is a passive device – it requires no cap and automatically seals upon disconnection.

The BD Texium™ Needle-Free Syringe has a unique closed male luer connector that is intended to be used with the currently marketed BD SmartSite™ Needle-Free Connector. As with the predicate device, the male luer design of the BD Texium™ Needle-Free Syringe includes an internal mechanism that causes the luer to seal when disconnected from a female luer. In doing so, it prevents the dripping or accidental spillage of fluids that otherwise occur when using a standard, unsealed male luer. When used with the BD SmartSite™ Needle-Free Connector, the BD Texium™ Needle-Free Syringe is intended to provide leak-free handling of potentially hazardous fluids, such as chemotherapy drugs. Furthermore, the BD Texium™ Needle-Free Syringe mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside of BD Texium™ Needle-Free Syringe/SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills (e.g., airtight, leak-free and drip-free).

Indication for Use

The BD Texium™ Needle-Free Syringe is a sterile, single-use closed system drug transfer device (CSTD) incorporating a bonded Texium™ Closed Male Luer and Syringe, intended for preparation and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-free Connector (NFC). When paired with devices containing a SmartSite™ NFC the BD Texium™ Needle-Free Syringe mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the BD Texium™ Needle-Free Syringe/SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills. (e.g.,

airtight, leak-free and drip-free).

Technological Characteristics and Substantial Equivalence

The following tables presents an overview of comparisons between the subject device and the predicate devices.

Table 1: Comparison between Subject BD Texium™ Needle-Free Syringe and Primary Predicate Texium™ Syringe (K071108)

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Primary) Texium™ Syringe (K071108)	Substantial Equivalence
FDA Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Different – additional product code, ONB, based on Indications for Use
FDA Regulation Name	Piston Syringe	Piston Syringe	Same
FDA Class	Class II	Class II	Same
FDA Product Code	FMF, **ONB**	FMF	Different – additional product code based on Indications for Use
Indication for Use	The BD Texium™ Needle-Free Syringe is a sterile, single-use closed system drug transfer device (CSTD) incorporating a bonded Texium™ Closed Male Luer and Syringe, intended for preparation and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-free Connector (NFC). When paired with devices containing a SmartSite™ NFC the BD Texium™ Needle-Free Syringe mechanically prohibits the transfer of environmental	The Texium™ Syringe is indicated for use by healthcare professionals for fluid aspiration/injection, reconstituting, dispensing/transferring, administering, and disposal of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids. The Texium™ Syringe is intended for use with the SmartSite® Needle Free Valve or standard open female luers.	Different – (updates to align with ONB product code) – air leakage, vacuum leakage, and fluid leakage testing was conducted to verify new claims. This difference does not raise new questions of safety or effectiveness, and the subject device is still substantially

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Primary) Texium™ Syringe (K071108)	Substantial Equivalence
	contaminants into the system and the escape of drug vapor concentrations outside the BD Texium™ Needle-Free Syringe/SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills. (e.g., airtight, leak-free and drip-free).		equivalent to the predicate device.
Principle of operation/mechanism of operation	The BD Texium™ Needle-Free Syringe has a unique male luer connector (BD Texium™ Closed Male Luer previously cleared under K223076) that is intended to be used with the currently marketed BD SmartSite™ Needle-Free Connector port and standard open female luers. When the BD Texium™ Needle-Free Syringe is disengaged from female luer, the membranes within the male luer connector act as tight seals that prevent leakage. When the male end of the BD Texium™ Needle-Free Syringe is connected to the BD SmartSite™ Needle-Free Connector port or any open female luer, the fluid path is open via direct contact with a spring-loaded actuator housed within the BD Texium™ Needle-Free Syringe. This provides bi-directional fluid flow through the BD Texium™ Needle-Free Syringe. When disconnected, the actuator of the BD Texium™	The Texium™ Syringe has a unique male luer connector (Texium™ Closed Male Luer previously cleared under K053049) that is intended to be used with the currently marketed SmartSite® Needle Free port and standard open female luers. When the Texium™ Syringe is disengaged from female luer, the membranes within the male luer connector (K053049) act as tight seals that prevent leakage. When the male end of the Texium™ Syringe is connected to the SmartSite® valve port or any open female luer, the fluid path is open via direct contact with a spring-loaded actuator housed within the Texium™ Syringe. This provides bi-directional fluid flow through the Texium™ Syringe. When disconnected, the actuator of the Texium™ Syringe is in a normally closed position that tightly seals the male luer internal diameter (ID) in two places. A secondary seal is provided	Equivalent (updates to align with ONB product code) – air leakage, vacuum leakage, and fluid leakage testing was conducted to verify new claims

	SUBJECT BD Texium™ Needle-Free Syringe	**PREDICATE (Primary) Texium™ Syringe (K071108)**	**Substantial Equivalence**
	Needle-Free Syringe is in a normally closed position that tightly seals the male luer internal diameter (ID) in two places. A secondary seal is provided between the closed male luer and the syringe via a split-septum membrane design feature of the BD Texium™ Closed Male Luer.	between the closed make luer and the syringe via a split-septum membrane design feature of the Texium™ closed male luer.	
Device Compatibility	SmartSite™ Needle-Free **Connector**	SmartSite™ Needle-Free Valve port or standard open female luers.	Equivalent
Method of Administration	Closed system drug transfer device (CSTD)	Closed system drug transfer device (CSTD)	Same
NON-DEHP	Yes	Yes	Same
Device Components	• BD Syringe • **BD Texium™ Closed Male Luer (K223076)** • Cap • Adhesive	• BD Syringe • Alaris Safety Male Luer (K053049) • Cap • Adhesive	Different – BD Texium™ Closed Male Luer was cleared under K223076. This difference does not raise new questions of safety or effectiveness, and the subject device is still substantially equivalent to the predicate device.
Volume sizes	• 3 mL • 5 mL • 10 mL • 20 mL • **30 mL** • **50 mL**	• 3 mL • 5 mL • 10 mL • 20 mL • 60 mL	Different – This difference does not raise new questions of safety or effectiveness, and the subject device is still substantially equivalent to the predicate device.

	SUBJECT BD Texium™ Needle-Free Syringe	**PREDICATE (Primary) Texium™ Syringe (K071108)**	**Substantial Equivalence**
No natural rubber latex	Yes	Yes	Same
Sterilization Method	Irradiation	Irradiation	Same
Sterility Assurance Level	10^-6	10^-6	Same
Sterilization Claim	**Content Sterile**	Fluid Path Sterile	Different – package integrity testing including seal strength, corner thickness, seal width, air volume, microbial barrier, dye test, and bubble leak testing was conducted to verify sterile barrier claim. This difference does not raise new questions of safety or effectiveness, and the subject device is still substantially equivalent to the predicate device.
Biocompatibility	Biocompatible for the intended use per ISO 10993-1	Biocompatible for the intended use per ISO 10993-1	Same
Non-Pyrogenic	Yes	Yes	Same
Shelf Life	3 Years	3 Years	Same
Materials of Construction	CML Male and Female Luer: Polycarbonate Actuator: Polypropylene, TPE, and Erucamide Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Cap: Low-density polyethylene	CML Male and Female Luer: Polycarbonate Actuator: Polypropylene, TPE, and Erucamide Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Cap: Low-density polyethylene	Same

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Primary) Texium™ Syringe (K071108)	Substantial Equivalence
	Syringe: Barrel and Plunger: Polypropylene Stopper: Polyisoprene Lubricant: Polydimethyl Siloxane	Syringe: Barrel and Plunger: Polypropylene Stopper: Polyisoprene Lubricant: Polydimethyl Siloxane	
Torque Withstand (Bond) Specifications	≥ 70 in-oz	≥ 70 in-oz	Same
Air Leakage Specifications	≥ 300kPa (For 3mL, 5mL and 10mL sizes) ≥ 200kPa (For 20 mL and 50 mL)	≥ 300kPa (For 3mL, 5mL and 10mL sizes) ≥ 200kPa (For 20 mL, 30 mL and 50 mL)	Same
Vacuum Leakage Specifications	< 40.00 µL	< 40.00 µL	Same

Table 2: Comparison between Subject BD Texium™ Needle-Free Syringe and Secondary Predicate Texium™ Closed Male Luer (K223076)

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Secondary) Texium™ Closed Male Luer (CML) (K223076)	Substantial Equivalence
FDA Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Different – subject device incorporates a syringe
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Different – subject device incorporates a syringe
FDA Class	Class II	Class II	Same
FDA Product Code	**FMF,** ONB	ONB	Different - subject device incorporates a syringe
Indication for Use	The BD Texium™ Needle-Free Syringe is a sterile, single-use closed system drug transfer device (CSTD) incorporating a bonded Texium™ Closed Male Luer and Syringe,	The BD Texium™ Closed Male Luer (CML) is a sterile, single-use closed system drug transfer device (CSTD) intended for the reconstitution, transfer and	Different – The Secondary Predicate does not include a bonded syringe. This difference does not raise new questions of safety or effectiveness, and the

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Secondary) Texium™ Closed Male Luer (CML) (K223076)	Substantial Equivalence
	intended for preparation and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-free Connector (NFC). When paired with devices containing a SmartSite™ NFC the BD Texium™ Needle-Free Syringe mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the BD Texium™ Needle-Free Syringe/SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills. (e.g., airtight, leak-free and drip-free).	administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-Free Connector (NFC). When paired with devices containing a SmartSite™ NFC the BD Texium™ CML mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the BD Texium™ CML/SmartSite™ NFC connection, thereby minimizing individual and environmental exposure to drugs, leaks, and spills. (e.g., airtight, leak-free and drip-free).	subject device is still substantially equivalent to the predicate device.
Principle of operation/mechanism of operation	The BD Texium™ Needle-Free Syringe has a unique male luer connector (BD Texium™ Closed Male Luer previously cleared under K223076) that is intended to be used with the currently marketed BD SmartSite™ Needle-Free Connector port and standard open female luers. When the BD Texium™ Needle-Free Syringe is disengaged from female luer, the membranes within the male luer connector act as tight seals that prevent leakage. When the male end of the BD Texium™	The BD Texium™ CML are fluid-transferring and utilize a patented triple membrane technique. The BD Texium™ CML is sealed off with an elastomeric seal in its tip, a sliding O-ring seal within the tip, and a slit membrane at the female end of the valve. The membranes are joined together, and transfer is made via an actuator. When the BD Texium™ CML is disengaged, these seals passively close to prevent leakage.	Different – The Secondary Predicate does not include a bonded syringe.

	SUBJECT BD Texium™ Needle-Free Syringe	PREDICATE (Secondary) Texium™ Closed Male Luer (CML) (K223076)	Substantial Equivalence
	Needle-Free Syringe is connected to the BD SmartSite™ Needle-Free Connector port or any open female luer, the fluid path is open via direct contact with a spring-loaded actuator housed within the BD Texium™ Needle-Free Syringe. This provides bi-directional fluid flow through the BD Texium™ Needle-Free Syringe. When disconnected, the actuator of the BD Texium™ Needle-Free Syringe is in a normally closed position that tightly seals the male luer internal diameter (ID) in two places. A secondary seal is provided between the closed male luer and the syringe via a split-septum membrane design feature of the BD Texium™ Closed Male Luer.	When the male end of the BD Texium™ CML is connected to a SmartSite™ NFC valve port or standard open female Luer, the fluid path is open via direct contact with a spring-loaded actuator housed within the BD Texium™ CML. This provides bi-directional fluid flow through the BD Texium™ CML. When disconnected, the actuator of the BD Texium™ CML is in a normally closed position that tightly seals the male Luer internal diameter (ID) in two places. A secondary seal is provided at the female end of the BD Texium™ CML via a split-septum membrane design feature of the piston. The optional priming cap is attached to the BD Texium™ CML at the end of the administration set to allow priming. When the actuator on the priming cap is depressed, air is vented through a hydrophobic membrane to open the Luer. The hydrophobic filter also prevents fluid from flowing past the cap when priming is complete	
Device Compatibility	SmartSite™ Needle-Free Connector	SmartSite™ Needle-Free Connector	Same
Method of Administration	Closed system drug transfer device (CSTD)	Closed system drug transfer device (CSTD)	Same

	SUBJECT BD Texium™ Needle-Free Syringe	**PREDICATE (Secondary) Texium™ Closed Male Luer (CML) (K223076)**	**Substantial Equivalence**
NON-DEHP	Yes	Yes	Same
Device Components / Materials	CML Male and Female Luer: Polycarbonate Actuator: Polypropylene, TPE, and Erucamide Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Cap: Low-density polyethylene **Syringe:** **Barrel and Plunger: Polypropylene** **Stopper: Polyisoprene** **Lubricant: Polydimethyl Siloxane**	CML Male & Female Luer: Polycarbonate Actuator: Polypropylene, TPE, and Erucamide Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Cap: Low-density Polyethylene	Same with respect to the CML and Cap. The Secondary Predicate does not have a Syringe.
Packaging	Individual device in peelable pouch. 50 pouches placed in shipper box for 30 mL and 50mL syringes. 100 pouches placed in shipper box for 3mL, 5 mL, 10 mL, 20 mL syringes. One (1) Directions for Use will be included in each shipper box. Black ink and webs included with primary packaging.	Individual device in peelable pouch. 50 pouches placed in dispenser box. Two (2) dispenser boxes in each shipper with one (1) Directions for Use in each shipper box. Black ink and webs included with primary packaging.	Different – Subject device does not have dispenser boxes and the units per box will vary depending on syringe sizes.
No natural rubber latex	Yes	Yes	Same
Sterilization Method	Irradiation	Irradiation	Same
Sterilization Claim	Content Sterile	Content Sterile	Same
Biocompatibility	Biocompatible for the intended use per ISO 10993-1	Biocompatible for the intended use per ISO 10993-1	Same
Non-Pyrogenic	Yes	Yes	Same
Shelf Life	3 Years	3 Years	Same

Substantial Equivalence Discussion:

Design verification testing was performed to demonstrate that the subject device is equivalent to the predicate

devices. All test results met their acceptance criteria and support that the BD Texium™ Needle-Free Syringe is safe and effective and is substantially equivalent to the predicate devices. The subject device and the predicate devices are sterilized via irradiation and are single use devices.

Both the subject and predicate devices have the same principle of operation. The primary technological differences between the subject device and the predicates are the addition of the newly cleared BD Texium™ Closed Male Luer (K223076) which substantiates the product code ONB. These differences were verified under K223076. BD Texium™ Needle-Free Syringe is claiming content sterile and the primary predicate claims fluid path sterile. Sterile barrier testing was performed to verify the claim.

Discussion of Non-Clinical Tests:

The BD Texium™ Needle-Free Syringe, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization [surface device: skin (<24 hours)]. Testing is performed in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Specific testing included:

- ISO 10993-2:2006 “Biological evaluation of medical device - Part 2: Animal welfare requirements”
- ISO 10993-4:2017 “Biological evaluation of medical device – Part 4: Selection of tests for interactions with blood”
- ISO 10993-5:2009 “Biological evaluation of medical device – Part 5: Tests for *in vitro* cytotoxicity”
- ISO 10993-10:2021 “Biological evaluation of medical device – Part 10: Tests for skin sensitization”
- ISO 10993-11:2017 “Biological evaluation of medical device – Part 11: Tests for systemic toxicity”
- ISO 10993-23:2021 “Biological evaluation of medical device – Part 23: Test for irritation”
- ISO 10993-12:2021 “Biological evaluation of medical device – Part 12: Sample preparation and reference materials”

Particulate Testing:

The BD Texium™ Needle-Free Syringe was tested to demonstrate the product meets particulate requirements of United States Pharmacopeia, National Formulary (USP), General Chapter <788>, Particulate Matter in Injections (Current Standard).

Sterilization and Shelf Life

The subject device is radiation sterilized and data supports a shelf-life claim of 3 years. Sterilization and shelf-life testing were completed in accordance with the following FDA recognized guidelines:

Sterilization:

- ISO 11137-1:2006/AMD 1:2013 “Sterilization of health care products — Radiation — Part 1:

Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1"
- ISO 11137-2:2013 "Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose"
- United States Pharmacopeia, National Formulary (USP), General Chapter <85>, Bacterial Endotoxins Test
- United States Pharmacopeia, National Formulary (USP), General Chapter <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests (2015)
- ANSI/AAMI ST72:2011 R:2016 – Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing.
- AAMI TIR 35:2016 Sterilization of health care products – Radiation sterilization – Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits.

Shelf-Life:
- ISO 11607-1 First Edition 2006-04-15 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]
- ISO 11607-2 First Edition 2006-04-15 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes [Including: Amendment 1 (2014)].
- Package testing included:
    - Package Integrity Test (dye leak test): ASTM F1929-15
    - Ink Legibility Test: Internal Testing
    - Visual Label Adhesion: Internal Testing
    - Microbial Barrier: ASTM F1608-16 and internal testing
    - Bubble Leak Integrity Test: ASTM F2096 and ASTM F2096-11
    - Seal Strength: ASTM F88/F88M-21
    - Seal Transfer Width: Internal testing
    - Standard Test Method for Thickness Measurement of Flexible Packaging Material: ASTM F2251-13

Performance Testing:

Performance testing for the BD Texium™ Needle-Free Syringe was executed with samples that were conditioned with an infusate representative of the worst-case hazardous drug that would be used with the subject device. Results of the testing showed that this worst-case infusate did not negatively impact the device's mechanical functions or performance characteristics. Testing for the conditioned BD Texium™ Needle-Free Syringe includes the following:

- Torque Withstand
- Leakage - actuated
- Vacuum Leakage - actuated

Performance testing also included:

- ISO 7886-1: 2017 "Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for manual use"

Microbial Ingress Testing:

Microbial ingress was performed based on the following FDA guidance document:

- Guidance for Industry and FDA staff; Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008

Additional testing was conducted to demonstrate:

- Harsh Infusates testing

Clinical Data:

There are no clinical data included in this submission.

Conclusion:

The information in this submission supports the safety and efficacy of the subject device for its intended use and demonstrates substantial equivalence with the predicate devices. The BD Texium™ Needle-Free Syringe differences compared to the predicate devices do not raise new questions about safety and effectiveness.