March 24, 2023

CareFusion
Elgin Oktay
Staff Regulatory Affairs Specialist
10020 Pacific Mesa Blvd
San Diego, California 92121

Re: K223076
Trade/Device Name: BD Texium™ Closed Male Luer
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: February 24, 2023
Received: February 24, 2023

Dear Elgin Oktay:

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,

David Wolloscheck, Ph.D.
Acting 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)*
K223076

Device Name
BD Texium™ Closed Male Luer

Indications for Use *(Describe)*

The BD Texium™ Closed Male Luer (CML) is a sterile, single-use closed system drug transfer device (CSTD) intended for the reconstitution, transfer and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ NFC.

The BD Texium™ Closed Male Luer (CML) is indicated for use by trained healthcare professionals within healthcare facilities who prepare and/or administer non-hazardous and hazardous drugs for adults, pediatrics and neonates.

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.

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K223076-
510(k)Summary

Submitter Information

Company Name:	CareFusion
Company Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121, USA
Name of contact Person:	Elgin Oktay, Staff Regulatory Affairs Specialist
Company Phone:	801-304-3908
Email:	Elgin.Oktay@bd.com
Date Prepared:	March 24, 2023

Subject 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

Predicate Device Identification

Trade/Proprietary Name:	Alaris® Safety Male Luer
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular Administration Set
Regulatory Class:	Class II
Product Code:	FPA
Classification Panel:	General Hospital
Premarket Notification:	K053049

Reason for the Submission

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

- New sterilization claim to “content sterile”
- Indications use updated to align with ONB product code
- Design modifications and material changes

- Packaging material changes

Device Description

The BD Texium™ CML is an airtight, leak-free and drip-free closed system drug transfer device (CSTD). 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. The BD Texium™ CML is a sterile single-use CSTD intended for the reconstitution, transfer and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ NFC.

Indication for Use

The BD Texium™ Closed Male Luer (CML) is a sterile, single-use closed system drug transfer device (CSTD) intended for the reconstitution, transfer and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ Needle-Free Connector (NFC).

The BD Texium™ Closed Male Luer (CML) is indicated for use by trained healthcare professionals within healthcare facilities who prepare and/or administer non-hazardous and hazardous drugs for adults, pediatrics and neonates.

Technological Characteristics and Substantial Equivalence

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

	SUBJECT **BD Texium™ CML** **(Subject Device)**	**PREDICATE** **Alaris® Safety Male Luer** **(K053049)**	**Substantial Equivalence**
FDA Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
FDA Class	Class II	Class II	Same
FDA Product Code	ONB	FPA	Different – product code "ONB" was not available at the time of predicate submission

	SUBJECT BD Texium™ CML (Subject Device)	PREDICATE Alaris® Safety Male Luer (K053049)	Substantial Equivalence
Principle of operation/mechanism of operation	The BD Texium™ Closed Male Luer (CML) is a sterile, single-use closed system drug transfer device (CSTD) intended for the reconstitution, transfer and administration of non-hazardous and 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).	The Safety Male Luer is indicated for use when reconstituting, dispensing/transferring, administering, and disposal of potential hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids. The Safety Male Luer is intended for use with the SmartSite Needle Free Valve port or standard open female luers.	Equivalent (updates to align with ONB product code) – air leakage, vacuum leakage, fluid leakage and residual fluid testing was conducted to verify new claims
Indication for Use	The BD Texium™ Closed Male Luer is a sterile, single-use closed system drug transfer device (CSTD) intended for the reconstitution, transfer and administration of hazardous and non-hazardous drugs when paired with the SmartSite™ NFC. The BD Texium™ Closed Male Luer is indicated for use by trained healthcare professionals within healthcare facilities who	The Safety Male Luer is indicated for use when reconstituting, dispensing/transferring, administering, and disposal of potential hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids. The Safety Male Luer is intended for use with the SmartSite Needle Free Valve port or standard open female luers.	Different – clarified the medical setting and user

	SUBJECT BD Texium™ CML (Subject Device)	PREDICATE Alaris® Safety Male Luer (K053049)	Substantial Equivalence
	prepare and/or administer non-hazardous and hazardous drugs for adults, pediatrics and neonates.		
Device Compatibility	SmartSite™ Needle-Free Connector	SmartSite™ Needle Free Valve port or standard open female luers.	Equivalent – device to be used with SmartSite™ Needle-Free Connector
Method of Administration	Closed system drug transfer device (CSTD)	Closed system drug transfer device (CSTD)	Same
NON-DEHP	Yes	Yes	Same
Device Components / Materials	CML Male & Female Luer: Polycarbonate (Makrolon RX1805) Actuator: Polyvel Erucamide (RE 20) Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Cap Polypropylene	SML Male & Female Luer: Polycarbonate Actuator: Polypropylene, TPE Piston: Silicone Seal Lubricant: Fluorosilicone Fluid Priming Cap Seal: Polypropylene Actuator: Acetal Membrane/Filter: PTFE	Different – biocompatibility testing was conducted to assess new materials; female luer body design changes were verified through ISO 80369-7 testing; actuator and male luer body design changes were verified through air leakage, vacuumed leakage and fluid leakage
Packaging	Individual device in peelable pouch. 50 pouches placed in dispenser box. 2 dispenser boxes in each shipper with one (1) Directions for Use. New black ink and webs included with primary packaging.	Individual device in peelable pouch with instructions. 50 pouches placed in dispenser box. 2 dispenser boxes in each shipper.	Different – packaging validation verifies new webs
No natural rubber latex	Yes	Yes	Same
Sterilization Method	Irradiation	Irradiation	Same

	SUBJECT BD Texium™ CML (Subject Device)	PREDICATE Alaris® Safety Male Luer (K053049)	Substantial Equivalence
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.
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
Duration of Use	7 days	7 days	Same
Disinfect with 70% Isopropyl Alcohol	Disinfect with 70% Isopropyl Alcohol	Disinfect with 70% Isopropyl Alcohol	Same
Priming Volume	0.17 ml	0.2 ml maximum	Equivalent – specification is within predicate specification
Flow Rate	≥4280 ml/hr, when activated with a minimum 3.2 mm (0.125") insertion depth	≥4756 ml/hr	Different – flow rate was conducted to verify rate
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 device. All test results met their acceptance criteria and support that the BD Texium™ CML is safe and effective and is substantially equivalent to the predicate Alaris® Safety Male Luer. The subject device and the predicate devices are sterilized via irradiation and are single patient use devices. Any differences in materials between the two products have been evaluated through ISO 10993 testing, which demonstrate material safety.

Both the subject and predicate devices have the same principle of operation. The primary technological differences between the subject device and the predicate are geometry and raw material changes to the male

and female luers, as well as the actuator with seal. These differences are verified through testing of air leakage, vacuum leakage, fluid leakage and ISO 80369-7 testing. The BD Texium™ CML is claiming content sterile and the predicate claims fluid path sterile. Sterile barrier testing was performed to verify the claim. The BD Texium™ CML has changes to the primary packing in that an Instructions for Use is being provided with each shipper box.

Discussion of Non-Clinical Tests:

The BD Texium™ CML, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (tissue contacting (indirect) prolonged (> 24 hours to 30 days)). 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 10993-3:2014 “Biological evaluation of medical device – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity”
- 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 10993-17:2002 “Biological evaluation of medical device – Part 17: Establishment of allowable limits for leachable substances”
- ISO 10993-18:2020 “Biological evaluation of medical device – Part 18: Chemical characterization of materials”
- ISO 10993-23:2021 “Biological evaluation of medical device – Part 23: Test for irritation”

Other standards followed included:

- ISO 8536-4:2019 “Infusion equipment for medical use – Part 4: Infusion Sets for Single Use Gravity Feed, Section 8 Chemical Requirements and Biological Requirements”

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Particulate Testing:

The BD Texium™ CML 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.

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:
    - Standard Test Method for Seal Strength of Flexible Barrier Materials: ASTM F88/F88M-21
    - Standard Test Method for Thickness Measurement of Flexible Packaging Material: ASTM F2251-13
    - Seal Transfer Width: internal testing
    - Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method: ASTM D6653/D6653M-13
    - Bubble Leak Detection Test: ASTM F2096 and ASTM F2096-11
    - Microbial Barrier: internal testing
    - Toluidine Blue Leak Detection Test: ASTM 3039-15

Performance Testing:

The BD Texium™ CML was tested to verify compliance with the relevant sections of the following standards:

- ISO 8536-4:2020 "Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed"
- ISO 80369-1:2018 "Small-bore connections for liquids and gases in healthcare applications – Part 1: General requirements"

- ISO 80369-7:2021 "Small-bore connections for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications"
- ISO 80369-20:2015 "Small-bore connections for liquids and gases in healthcare applications – Part 20: Common test methods"

Performance testing was conducted per below:

- Leakage by pressure decay
- Sub-Atmospheric Air Pressure Leakage
- Stress Cracking
- Resistance to Separation from Axial Load
- Resistance to Separation from Unscrewing
- Resistance to Overriding
- Air leakage
- Vacuum leakage
- Fluid leakage
- Residual fluid
- Flow rate

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: Device tests for multiple days with worst case infusates

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 device. The BD Texium™ CML differences in geometry, materials and sterilization claim do not raise new questions about safety and effectiveness.