December 18, 2021

B. Braun Medical Inc.
Kimberly Smith
Sr. Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, Pennsylvania 18109-9341

Re: K212842
Trade/Device Name: Microvolume Luer Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: December 15, 2021
Received: December 17, 2021

Dear Kimberly Smith:

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,

Gang Peng For
Payal Patel
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)*
K212842

Device Name
Microvolume Luer Access Device

Indications for Use *(Describe)*
The Microvolume Luer Access Device is a valve intended for the aspiration, injection, or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The Microvolume Luer Access Device may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 10ml/sec.

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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510(k) Summary
K212842

I. Submitter Information

Name: B. Braun Medical Inc.
Address: 901 Marcon Boulevard
Allentown, PA 18109-9341
Contact Person: Kimberly Smith
Sr. Regulatory Affairs Specialist
Telephone Number: (610) 596-2326
Fax Number: (610) 266-4962
Email kim.smith@bbraunusa.com
Date Prepared: January 13, 2022

II. Device Name and Classification

Device Trade Name: Microvolume Luer Access Device
Common Name: Luer Access Device, Needleless Connector; Needle-free Injection Site; Needle-free Luer Access Device; Needle-free connector; Valve
Classification Name: Intravascular administration set; §21 CFR 880.5440
Regulatory Class Class II
Product Code: FPA

III. Predicate Device

Device Trade Name: Caresite Luer Access Device
Common Name: Needleless Connector; Needle-free Injection Site; Needle-free Luer Access Device
Classification Name: Intravascular administration set; §21 CFR 880.5440
Regulatory Class Class II
Product Code: FPA
510(k) Number: K140311, B. Braun Medical Inc.

Reference Device
Trade Name: Clave Connector
Classification Name: Intravascular administration set; §21 CFR 880.5440
510(k) Number: K970855, ICU Medical, Inc.

IV. Device Description

The Microvolume Luer Access Device (LAD) consists of a body, piston, spike/nut, and a male luer lock cover. The Microvolume LAD is a neutral displacement needleless connector intended to provide needle-free access to IV gravity sets, pump sets and extension sets for the administration of IV fluids and blood. The Microvolume LAD may be used with a power injector. The Microvolume LAD is individually packaged and supplied as a sterile, non-pyrogenic, single use disposable device.

V. Indications for Use / Intended Use

Indications for Use

The Microvolume Luer Access Device is a valve intended for the aspiration, injection, or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The Microvolume Luer Access Device may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 10ml/sec.

Intended Use

The intended use of the Microvolume Luer Access Device is to provide a sterile needle-free fluid pathway for the administration or aspiration of blood, IV therapy, or medications as prescribed by the physician. Fluids are administered to the patient through a catheter or cannula. The device can be utilized as a conduit between two devices, in addition to being used to deliver contrast media via power injection. This is a general use device that may be used for any patient population with consideration given to the adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

VI. Comparison of Technological Characteristics with the Predicate Device

The similarities and differences of the technological characteristics between the predicate and the subject device are summarized below.

Similarities:

- The subject Microvolume Luer Access Device and the predicate device are identical in their intended use.
- Mode of fluid delivery is the same for both the predicate and subject devices. Both devices are used for gravity/pump administration.
- Conditions of use are the same for both the predicate and subject devices. Both devices are used by the same type of healthcare professionals under the same conditions of use.
- Sterilization method, SAL Level and sterilization cycle are the same for both the predicate and subject devices.
- Interfaces are similar between the subject device and predicate device. Both devices contain threaded female and male ports intended for use with associated luers.
- Mechanical and Performance Specifications are similar between the subject device and predicate device. The predicate device performance testing and referenced standards were utilized as a guide to establish the testing for the subject device. The subject device meets all the standards that were met by the predicate. Additional standards were considered for performance testing of the subject device.

Differences:

- Principle of operation is different but achieves the same intended use. The difference does not raise different questions of safety and effectiveness and is evaluated by design verification testing.
- Physical characteristics and dimensions are different but do not impact the intended use. The differences do not raise different questions on safety and effectiveness and is evaluated by performance testing.
- Displacement Volume is different but does not impact the intended use. The difference does not raise different questions on safety and effectiveness and is evaluated by performance testing.

	Proposed Device Microvolume Luer Access Device	Predicate Device (K140311) Caresite Luer Access Device	Comparison
Manufacturer	B. Braun Medical Inc.	B. Braun Medical Inc.	Same
Intended Use	The intended use of the Microvolume Luer Access Device is to provide a sterile needle-free fluid pathway for the administration or aspiration of blood, IV therapy, or medications as prescribed by the physician. Fluids are administered to the patient through a catheter or cannula. The device can be utilized as a conduit between two devices, in addition to being used to deliver contrast media via power injection. This device may be used for any patient population with consideration given to the adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.	The intended use of the Caresite Luer Access Device is to provide a sterile needle-free fluid pathway for the administration or aspiration of blood, IV therapy, or medications as prescribed by the physician. Fluids are administered to the patient through a catheter or cannula. The device can be utilized as a conduit between two devices, in addition to being used to deliver contrast media via power injection. This device may be used for any patient population with consideration given to the adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.	Same
Indications for Use	The Microvolume Luer Access Device is a valve intended for the aspiration, injection, or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The Microvolume Luer Access Device may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 10ml/sec.	The Caresite Luer Access Device is a valve intended for the aspiration, injection, or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The Caresite Luer Access Device may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 15ml/sec.	Different Difference in power injector maximum flow rate falls within the indications for use of the predicate device, therefore; the two devices have equivalent indications for use.
Mode of Fluid Delivery	Gravity/Pump Administration	Gravity/Pump Administration	Same
Components of Device	3-piece assembly containing: 1. Body 2. Piston 3. Luer Nut 4. Male luer lock vented cover	3-piece assembly containing: 1. Body 2. Piston 3. Luer Nut 4. Male luer lock vented cover	Same

Summary of nonclinical tests for determination of substantial equivalence	• Flow Rate & Capacity Attributes • Seal and Snap Tests • Durability Testing • Seal Tests – Post Durability • Power Injection • 7 Day IPA & CHG Compatibility • IPA Exposure, Infusate Compatibility • Duration & Connector Removal • ISO 80369-7 Compliance Testing • Associate Male ID Testing • 7 Day Disinfection Cap Compatibility with Swab Cap, Curos Jet, and CareCap. Disinfection Cap Valve Activation • Particulate Contamination • Cap Assessment after Ship Test • Mechanical Hemolysis • Microbial Ingress Testing • Tensile Testing • Real-Time Aging • Displacement Volume • Flushability • Ship Testing	• Flow Rate & Capacity Attributes • Seal and Weld Tests • Durability Testing • Seal Tests – Post Durability • Power Injection • 4 Day IPA & CHG Compatibility • IPA Exposure, Infusate Compatibility • Duration • ISO 594 Compliance Testing • Associate Device Testing • Mechanical Hemolysis • Microbial Ingress Testing • Flushability • Ship Testing	Different The additional nonclinical tests do not raise different questions on safety and effectiveness, as demonstrated by performance testing.
Physical Characteristics	Male Luer ID = 0.0673 in. Male Luer OD = 0.1565in. w/0.060 in/in taper Female ID = 0.1669in. Priming Volume = 0.0345 mL, average Residual Volume = 0.052 mL, average	Male Luer ID = 0.080 in. Male Luer OD = 0.1565 in. w/0.060 in/in taper Female ID = 0.1669 in. Priming Volume = 0.22 mL, average Residual Volume = 0.20 mL, average	Different The physical characteristics do not raise different questions on safety and effectiveness, as demonstrated by performance testing.
Materials	• Body - Copolyester • Piston - Silicone Elastomer, Self-lubricating • Luer Nut - ABS • Male Luer Lock Vented Cover - Polyethylene	• Body - Polycarbonate • Piston - Silicone Elastomer, Self-lubricating • Luer Nut - Polycarbonate • Male Luer Lock Vented Cover - Polyethylene	Different The difference in materials do not raise different questions on safety and effectiveness as demonstrated by performance testing and biocompatibility.
Patient Contact category/duration	Externally Communicating, Blood Path Indirect prolonged exposure	Externally Communicating, Blood Path Indirect prolonged exposure	Same
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Same
Sterilization	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Same

VII. Performance Data

Performance Testing Bench

Functional performance bench testing was conducted to demonstrate that the Microvolume Luer Access Device performs as intended. No clinical was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device. The following nonclinical performance tests were conducted in support of the substantial equivalence determination:

Standard	Test Performed
ISO 8536-4:2019	• Flow Rate & Capacity Attributes • Seal and Snap Tests • Seal Test • Seal Tests – Post Durability • Particulate Contamination • Associate Male ID Testing • Tensile Testing
ISO 8536-8:2015	• Seal and Snap Tests • Seal Test • Seal Tests – Post Durability • Associate Male ID Testing • Tensile Testing
ISO 8536-9:2015	• Tensile Testing
ISO 8536-10:2015	• Seal and Snap Tests • Seal Test • Seal Tests – Post Durability • Associate Male ID Testing • Tensile Testing
ISO 10993-4:2017 ISO 10993-12:2021	• Mechanical Hemolysis
ISO 80369-7:2021	• Dimensional requirements for Luer connectors • Fluid leakage • Sub-atmospheric pressure air leakage • Stress cracking • Resistance to separation from axial load • Resistance to separation from unscrewing • Resistance to overriding
ISO 11607-1:2020 ASTM F1980-16 ASTM F1886M-16 ASTM D4169-16 ASTM D4332-14 ASTM F88/F88M-15 ASTM F1929-15 ASTM F2096-11 ASTM F2638-18	• Sterile Barrier System Validation

USP <161> ANSI/AAMI ST72:2019	• Pyrogen
ISO 11135:2014/AMD 1:2018	• Sterilization Validation
ISO 10993-7:2008/AMD 1:2019	• EO Residuals
B. Braun Medical Inc. device performance test methods	• Durability • Microbial Ingress • Displacement Volume • Power Injection • 7 Day IPA & CHG Compatibility • IPA Exposure, Infusate Compatibility • Duration & Connector Removal • Disinfection Cap 7-Day Compatibility with Swab Cap, Curos Jet, and CareCap. Disinfection Cap Valve Activation • Cap Assessment after Ship Test • Flushability
USP <788>	• Particulate Contamination

Biocompatibility Testing

The Microvolume Luer Access Device was evaluated according to ISO 10993-1:2018. The following biocompatibility testing was performed with the reference standard utilized:

Test Performed	Standard
Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5:2009
Guinea Pig Maximization Sensitization Test	ISO 10993-10:2010
Intracutaneous Study in Rabbits	ISO 10993-10:2010
Acute Systemic Toxicity Study in Mice	ISO 10993-11:2017
Subacute Toxicity Study in Rats	ISO 10993-11:2017
Hemocompatibility – Hemolysis	ISO 10993-4:2017
Partial Thromboplastin Time (PTT) Assay	ISO 10993-4:2017
Heparinized Blood Platelet and Leukocyte Count Assay	ISO 10993-4:2017
Complement Activation Assay	ISO 10993-4:2017
Material Mediated Pyrogenicity in Rabbits	ISO 10993-11:2017
FTIR – Confirmation of Materials	ASTM E1252
Section 8; Annex B - Chemical Requirements	ISO 8536-4:2020

VIII. Substantial Equivalence

Intended Use/Indications for Use - Discussion of differences and similarities

The intended use of the proposed and the predicate device are identical. The indications for use of the proposed and the predicate device are equivalent and do not create a new intended use:

- Both devices are valves intended for the administration or aspiration of blood, IV therapy, or medications as prescribed by the physician.
- Both devices can be utilized as a conduit between two devices, in addition to being used to deliver contrast media via power injection.
- Both devices are general used device and may be used for any patient population with consideration given to the adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.
- The indications for use of the proposed device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use.

The differences in the Indications for Use do not affect safety and effectiveness and do not alter the intended use of the proposed device:

- The Indications for Use of the proposed device allows for use with a power injector at a maximum pressure of 400 psi and a maximum flow rate of 10ml/sec and the predicate allows for use with a power injector at a maximum pressure of 400 psi and a maximum flow rate of 15ml/sec.
- Both devices are used by the same type of healthcare professionals under the same conditions of use.
- Both devices have the same fundamental scientific technology.

Technological Characteristics – Discussion of Differences

Based on the performance data, the Microvolume Luer Access Device was found to have a safety and effectiveness profile similar to the predicate device. The technological characteristics of the proposed device are substantially equivalent to the predicate device as compared in sections VI and VII above.

Conclusion on Substantial Equivalence

The proposed Microvolume Luer Access Device has the same intended use and equivalent Indications for Use as the predicate device. The proposed device has the same mode of fluid delivery as the predicate. The proposed device has similar technological characteristics to the predicate, meets the same relevant performance specifications as the predicate, and the descriptive and performance information provided within this premarket notification demonstrates that:

- any differences do not raise different questions of safety and effectiveness than that of the predicate device; and
- the proposed device is as safe and effective as the legally marketed predicate device.

The Microvolume Luer Access Device is substantially equivalent to the predicate device.