September 24, 2021

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

Re: K202618
Trade/Device Name: IV Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: August 25, 2021
Received: August 26, 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,

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)*
K202618

Device Name
IV Administration Sets

Indications for Use *(Describe)*
IV Sets are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system.
These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Extension Sets may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids and medications.
These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

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 K202618

DATE:	September 23, 2021
SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 Contact: Kimberly Smith Phone: (610) 596-2326 Fax: (610) 266-4962 E-mail: kim.smith@bbraunusa.com
TRADE OR PROPRIETARY DEVICE NAME:	IV Administration Sets
COMMON NAME:	Intravascular Administration Set
CLASSIFICATION:	Intravascular administration set Class II, Product Code FPA, 21 CFR §880.5440
PREDICATE DEVICE:	K170595, IV Administration Sets, B. Braun Medical Inc. Class II, Product Code FPA, 21 CFR §880.5440 K153293, Extension Set, B. Braun Medical Inc. Class II, Product Code FPA, 21 CFR §880.5440
REASON FOR 510(K):	The following changes are addressed in this submission. • Indications for Use that include both IV Sets and Extension Sets • Addition of a flow regulator component • Addition of a 10 drop drip chamber component • Addition of a y-connector component

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Description

IV Administration Sets are gravity, single use, disposable, IV sets and extension sets. IV Administration Sets are used to deliver fluids from a container into a patient's vascular system.

Extension sets are connected to primary IV administration sets to add length and provide clamping capabilities or added to an intravascular catheter hub as a conduit for flow to and from the catheter and are used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids and medications.

These sets may be comprised of various components which are broadly used throughout industry including insertion spike, drip chamber, clamp, luer access device, check valve, tubing, luer connections (connector/adaptor), y-connector, and flow regulator.

Indications for Use
IV Sets are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system.
These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Extension Sets may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids and medications.
These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Intended Use
Delivery of fluids from a container into a patient's vascular system.

Substantial Equivalence
The IV Administration Sets are substantially equivalent to the B. Braun Medical Inc. IV Administration Sets (K170595) and the B. Braun Medical Inc. Extension Sets (K153293) predicate devices.

The IV Administration Sets presented in this submission have the same intended use, the same principle of operation, the same fundamental scientific technology, and similar Indications for Use as the predicate devices. They are comprised of similar component types and meet the same relevant performance specifications as the predicate devices.

The differences between the predicate devices and the subject devices are the addition of a flow regulator component, a 10 drop drip chamber component, and a y-connector component. Additionally, the extension sets are not indicated for use with blood or blood products or for use with power injectors.

The following Tables 1 and 2 summarize the comparison between the subject devices and the predicate devices.

Table 1-Comparison of Proposed and Predicate Devices IV Administration Sets

	Proposed Device (K202618) IV Administration Sets	Predicate Device (K170595) IV Administration Sets	Comparison of Differences and Similarities
Manufacturer	B. Braun Medical Inc.	B. Braun Medical Inc.	Same
Intended Use	Delivery of fluids from a container into a patient's vascular system.	Delivery of fluids from a container into a patient's vascular system.	Same

Table 1-Comparison of Proposed and Predicate Devices IV Administration Sets

	Proposed Device (K202618) IV Administration Sets	Predicate Device (K170595) IV Administration Sets	Comparison of Differences and Similarities
Indications for Use	IV Sets are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.	The IV Administration Sets are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.	Same
Mode of Fluid Delivery	Gravity Administration	Gravity Administration	Same
Set Components	Sets configured with various industry standard components including: insertion spike drip chamber PVC tubing luer connections (connector/ adaptor) needleless luer access device clamps check valve flow regulator y-connector	Sets configured with various industry standard components including: insertion spike drip chamber PVC tubing luer connections (connector/ adaptor) needleless luer access device clamps check valve manifold stopcocks	Different components. The proposed devices contain a flow regulator and y-connector component. Both the predicate and subject devices configurations achieve the same intended use.
Summary of nonclinical tests for determination of substantial equivalence	• Priming Test / Air Visualization • Flow Rate and Occlusion • Positive Pressure • Negative Pressure • Dynamic Tensile • Static Tensile • Leakage • Clamp Pressure Resistance • Slide Clamp Pressure • Stability and Accuracy • Particulate Contamination • Microbial Ingress • Y-Connector Injection Site Assembly pressure and reseal • Microbial Ingress	• Priming Test / Air Visualization • Flow Rate and Occlusion • Positive Pressure • Dynamic Tensile • Static Tensile • Luer Compliance	Additional verification testing was performed on the proposed device when compared to the predicate. Verification results confirm that the differences in the set components do not raise new or different questions of safety and effectiveness.

Table 1-Comparison of Proposed and Predicate Devices IV Administration Sets

	Proposed Device (K202618) IV Administration Sets	Predicate Device (K170595) IV Administration Sets	Comparison of Differences and Similarities
Materials	ABS, Silicone, MABS, PC, LDPE, HDPE, Polyisoprene, Cyrolite, Synthetic Polyisoprene, Acrylic, Nylon, PVC, Polyamide, Stainless steel, Polypropylene, Acetal, Cyclohexanone, Methyl Ethyl Ketone (MFK), Methylene Chloride (MC), Tetrahydrofuran (THF)	PVC, LDPE, HDPE, PC, PP, ABS, Stainless steel, MABS, Acetal, Acrylic, Nylon, High impact polystyrene, Polyamide, Santoprene, Synthetic Polyisoprene, Cyrolite, Parylene-N, Silicone rubber, Liquid silicone rubber, Polydimethylsiloxane, Cyclohexanone, Methylene Chloride(MC), Tetrahydrofuran(THF)	Materials were evaluated in accordance with ISO 10993-1 for both the predicate and subject devices. The different materials do not raise different questions of safety and effectiveness.
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

Table 2: Comparison of Proposed and Predicate Devices IV Administration Extension Sets

	Proposed Device (K202618) IV Administration Extension Sets	Predicate Device (K153293) Extension Sets	Comparison of Differences and Similarities
Manufacturer	B. Braun Medical Inc.	B. Braun Medical Inc.	Same
Intended Use	Delivery of fluids from a container into a patient's vascular system.	Delivery of fluids from a container into a patient's vascular system.	Same
Indications for Use	Extension Sets may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids and medications. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.	B. Braun Extension Sets may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products. Select sets may be used with power injector procedures or a maximum pressure of 400 psi and a maximum flow rate of 15 mL per second. B. Braun's optional stabilization component on an extension set provides stability to an intravascular catheter by supporting the patient connector. B. Braun Extension sets may be used for any patient population.	Equivalent –Both the predicate and subject devices may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids and medications and both may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The proposed devices are not indicated for use with blood or blood products and are not intended to be used for power injection. The proposed devices do not contain a stabilization component. The differences in the indications for use does not result in a new intended use.
Mode of Fluid Delivery	Gravity Administration	Gravity or Power Injection	The proposed devices are not intended for power injection.
Set Components	Sets configured with various industry standard components including: PVC tubing luer connections (connector/ adaptor) Spin-lock connector needleless luer access device flow regulator y-connector clamps check valve	Sets configured with various industry standard components including: PVC tubing Luer Slide Clamp Stabilization Component Spin-lock connector (patient connector/male luer adapter)	Different components. The proposed devices contain a flow regulator and y-connector. The differences between the subject and predicate configurations do not raise different questions of safety and effectiveness. Both the predicate and subject devices configurations achieve the same intended use.

Table 2: Comparison of Proposed and Predicate Devices IV Administration Extension Sets

	Proposed Device (K202618) IV Administration Extension Sets	Predicate Device (K153293) Extension Sets	Comparison of Differences and Similarities
Summary of nonclinical tests for determination of substantial equivalence	• Priming Test / Air Visualization • Flow Rate and Occlusion • Leakage • Positive Pressure • Negative Pressure • Dynamic Tensile • Static Tensile • Clamp Pressure Resistance • Slide Clamp Pressure • Stability and Accuracy • Particulate Contamination • Y-Connector Injection Site Assembly pressure and reseal • Microbial Ingress	• Stabilization Component Performance • Visual • Catheter Angle • Flow Rate-No Catheter • Tape Removal • Occlusion • Negative Pressure • Positive Pressure • Clamp and Positive Pressure • Tensile Strength • Power Injection • Mechanical Hemolysis - Aspiration and Injection • Luer Connection • Gauging • Liquid and Air Leakage • Separation Force • Stress Cracking • Collar Retention • Joint Qualification • Particulate Contamination	Verification testing was performed on the proposed device. Verification results confirm that the differences in the set components do not raise new questions of safety and effectiveness.
Materials	ABS, Silicone, MABS, PC, LDPE, HDPE, Polyisoprene, Cyrolite, Synthetic Polyisoprene, Acrylic, Nylon, PVC, Polyamide, Stainless steel, Polypropylene, Acetal, Cyclohexanone, Methyl Ethyl Ketone (MFK), Methylene Chloride (MC), Tetrahydrofuran (THF)	PVC, LDPE, HDPE, PC, PP, ABS, Methylene Chloride (MC), Tetrahydrofuran (THF)	Materials were evaluated in accordance with ISO 10993-1 for both the predicate and subject devices. The different materials do not raise different questions of safety and effectiveness.
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

Non Clinical Performance Testing

The non clinical performance tests successfully completed are listed under the applicable standard.

Standard

ISO 8536-4:2019, *"Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed"*
Tests - Positive Pressure Test of IV Set, Negative Pressure Test of IV Set, Static Tensile Test, Visual Test, Particulate Contamination Test

Standard
***ISO 8536-13:2016**, "Infusion equipment for medical use - Part 13: Graduation flow regulators for single use with fluid contact"*
Tests – Flow Rate Accuracy Test, Flow Rate Stability Test, Positive Pressure Test of Rate Control Device at Various Dial Settings, Negative Pressure Test of Rate Control Device at Various Dial Settings

Standard
***ISO 8536-14:2016**, "Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact"*
Tests - Clamp Pressure Resistance, Slide Clamp Pressure

Standard
USP<788>
Test - Particulate Matter in Injections

Standard
***ISO 10993-1:2018**, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*
Tests - Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Sub-Chronic Toxicity, Hemocompatibility, Material Mediated Rabbit Pyrogen

Standard
***ISO 11135,** "Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices"*

Additional tests performed per internal B. Braun procedure

- Priming and Flow Rate
- Y-Connector Injection Site Assembly pressure and reseal
- Microbial Ingress

Results of the testing demonstrate that the proposed devices can be used according to their intended use.

Clinical Tests
Not applicable

CONCLUSION

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The results of testing and content within this traditional

510(k) submission demonstrates that the proposed IV Administration Sets are substantially equivalent to the predicate devices.