March 19, 2020

B. Braun Medical Inc.
Angela Caravella
Sr. Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K191658
Trade/Device Name: IV Sets not made with PVC
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: February 14, 2020
Received: February 18, 2020

Dear Angela Caravella:

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,

Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191658

Device Name
IV Sets not made with PVC

Indications for Use *(Describe)*
The IV Administration Sets not made with PVC are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system.

The IV Extension Sets not made with PVC may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products.

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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5. 510(k) SUMMARY

510(k) Number: K191658

Date: March 17, 2020

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Angela J. Caravella
Sr. Regulatory Affairs Specialist
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DEVICE NAME: IV Sets not made with PVC

COMMON NAME: Intravascular Administration Set

CLASSIFICATION: Set, Administration, Intravascular, 21 CFR 880.5440, Class II, Product Code FPA

PREDICATE DEVICES: K170595, IV Administration Sets, B. Braun Medical Inc**.**
K153293, Extension Set, B. Braun Medical Inc.

DEVICE DESCRIPTION:

The IV Sets not made with PVC are gravity, single use, disposable, IV administration sets and extension sets. IV administration sets are used to deliver fluids from a container into a patient's vascular system. The IV extension sets are used for direct injection, intermittent infusion, continuous infusion or aspiration.

These sets may be comprised of various components, which are broadly used throughout industry including insertion spikes, drip chambers, clamps, needleless luer access devices, check valves, tubing, filters, stopcocks and luer connections (connector, adaptor).

The proposed sets have not been made with polyvinylchloride (PVC). The tubing in these sets is made of polyurethane (PUR).

INDICATIONS FOR USE

The IV Administration Sets not made with PVC are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system.

The IV Extension Sets not made with PVC may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products.

SUBSTANTIAL EQUIVALENCE:

The IV Sets not made with PVC 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 predicate devices used for comparison to the IV Sets not made with PVC were utilized to demonstrate the substantial equivalence in indications for use, intended use, and design between the proposed device and the predicate devices.

The proposed IV Sets not made with PVC include IV Administration Sets and IV Extension Sets. The indications for use for the proposed IV Sets includes the indications for use from the predicate devices; IV Administration Sets and Extension Sets. The only exception is the predicate Extension Set indication for power injection compatibility. The proposed IV Sets not made with PVC are not indicated for power injection. This reduction in indications for use does not introduce a new intended use.

The intended use of the proposed IV Administration Sets not made with PVC is identical to the predicate IV Administration Sets: Delivery of fluids from a container into a patient's vascular system. The intended use of the proposed Extension Sets not made with PVC is identical to the predicate Extension Sets: Direct injection, intermittent infusion, continuous infusion or aspiration.

Comparison of Technological Characteristics with the Predicate Devices

The IV Sets not made with PVC possess similar technological characteristics to the predicate devices B. Braun Medical Inc. IV Administration Sets cleared under K170595 and B. Braun Medical Inc. Extension Sets cleared under K153293.

The two main differences between the proposed and predicate devices is in componentry: the proposed device tubing material utilizes polyurethane (PUR) within its formulation instead of polyvinylchloride (PVC) and some of the proposed devices contain an additional in-line AirStop filter. These technological differences between the proposed and predicate devices do not raise new issues of safety and effectiveness. Non-clinical testing was performed to demonstrate the differences

did not raise new questions.

A table summarizing the comparison between the IV Sets not made with PVC to the predicate devices is provided below:

Substantial Equivalence - Comparison of Proposed Device with Predicate Devices			
	Proposed Device IV Sets not made with PVC	**Predicate Device** (K170595) IV Administration Sets	**Predicate Device** (K153293) Extension Sets
Intended Use	The IV Administration Sets not made with PVC are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. The IV Extension Sets not made with PVC are intended for direct injection, intermittent infusion, continuous infusion or aspiration.	Delivery of fluids from a container into a patient's vascular system.	Intended for direct injection, intermittent infusion, continuous infusion or aspiration.
Indications for Use	The IV Administration Sets not made with PVC are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. The IV Extension Sets not made with PVC may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products.	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	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 to 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.

Substantial Equivalence - Comparison of Proposed Device with Predicate Devices			
	Proposed Device IV Sets not made with PVC	**Predicate Device** (K170595) IV Administration Sets	**Predicate Device** (K153293) Extension Sets
		therapy.	B. Braun Extension Sets may be used for any patient population.
Mode of Fluid Delivery	Gravity	Gravity	Gravity or Power Injection
Set Components	Sets configured with various industry standard components including: insertion spike drip chamber PUR tubing luer connections (connector/adaptor) needleless luer access device stopcocks clamps check valve in line filters	Sets configured with various industry standard components including: insertion spike drip chamber PVC tubing luer connections (connector/adaptor) manifold needleless luer access device stopcocks clamps check valve	PVC tubing Luer Slide clamp Stabilization Component Spin-lock connector (patient connector/male luer adapter)
Materials	PUR, LDPE, HDPE, PC, PP, PS, PE, MABS, SBC/SBS, PTFE, Acrylic, Nylon, Borosilicate glass fiber paper, High impact polystyrene, Polyamide, Polyethersulphone, Polyarylsulphone, Polyvinylpyrrolidone, Synthetic Polyisoprene, Cyrolite, Parylene-N, Silicone rubber, Liquid Silicone rubber, Polydimethylsiloxane, Cyclohexanone, Methyl Ethyl Ketone (MEK), 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)	PVC, LDPE, HDPE, PC, PP, ABS, Methylene Chloride (MC), Tetrahydrofuran (THF)
Summary of non-clinical	• Visual Inspection • IV Spike function	• Luer Compliance • Priming Test / Air	• Stabilization Component

Substantial Equivalence - Comparison of Proposed Device with Predicate Devices			
	Proposed Device IV Sets not made with PVC	**Predicate Device** (K170595) IV Administration Sets	**Predicate Device** (K153293) Extension Sets
tests for determination of substantial equivalence	• Closure-piercing device dimensions • Priming/Air Visualization • Air-inlet device function • Flow Rate • Filter performance • Clamp (roller and slide) function • Drip Chamber Drop former function • Joint/leakage (occlusion, positive pressure, negative pressure, static tensile, dynamic tensile) • Particulate Contamination (USP 788 and ISO 8536-4) • Microbial Ingress (leveraged from K140311)	Visualization • Flow rate and occlusion • Positive pressure test • Dynamic Tensile test • Static Tensile test	Performance • Visual • Catheter Angle • Flow Rate- No Catheter • Flow Rate - With 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
Patient Contact category / duration	Externally Communicating, Blood Path Indirect prolonged exposure	Externally Communicating, Blood Path Indirect prolonged exposure	Externally Communicating, Blood Path Indirect prolonged exposure
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Conforms to ISO 10993-1
Sterilization	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}

Non Clinical Performance Testing

Non-clinical performance testing was completed with the proposed IV Sets not made with PVC to demonstrate that the sets perform as intended. The test results demonstrated that the proposed device considered the following standards:

ISO 8536-4: *"Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed"*

ISO 8536-14: *"Infusion Equipment For Medical Use – Part 14: Clamps and flow regulator for transfusion and infusion equipment without fluid contact"*

ISO 10993-1: *"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

Cytotoxicity
Sensitization
Irritation
Systemic Toxicity
Hemocompatibility
Genotoxicity
Material Mediated Pyrogenicity
SubChronic Toxicity

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

ISO 80369-7, "*Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications"*

ASTM F2096, *"Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)"*

In addition, the following functional and performance tests were successfully completed to demonstrate that the IV Administration Sets perform as intended.

- Particulate Contamination (USP 788 and ISO 8536-4)
- Microbial Ingress (leveraged from K140311)
- Bacterial Endotoxin Testing

Results of the testing demonstrate that the proposed device can be used according to its intended use. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

CONCLUSION:

Results of testing and content within this traditional 510(k) submission demonstrates that the proposed IV Sets not made with PVC are substantially equivalent to the predicate devices.