August 22, 2019

B. Braun Medical Inc.
Nancy Skocypec
Associate Director, Regulatory Affairs
901 Macon Blvd
Allentown, Pennsylvania 18109

Re: K170595
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: February 24, 2017
Received: February 28, 2017

Dear Nancy Skocypec:

This letter corrects our substantially equivalent letter of November 7, 2017.

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 Alan M. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170595

Device Name

IV Administration Sets

Indications for Use *(Describe)*

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.

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 K170595

DATE: November 2, 2017

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

Contact: Nancy Skocypec
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Fax: (610) 266-4962
E-mail: nancy.skocypec@bbraun.com

DEVICE NAME: IV Administration Sets

COMMON NAME: IV Administration Sets

CLASSIFICATION: Class II, Product Code FPA, 21 CFR 880.5440

PREDICATE DEVICE: IV Administration Set with Hand Pump, B. Braun Medical, Inc., K140838, Class II, FPA, 21 CFR 880.5440

Description
IV Administration Sets are single use, disposable, intravenous administration sets used to deliver fluids from a container into a patient's vascular system. 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, stopcock, manifold, tubing, luer connections (connector, adaptor), and filter. IV Administration sets are configured to ensure the intended use of the device is met. The proposed device, IV Administration Sets are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system.

Indications for Use
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.

Substantial Equivalence
Predicate Device – IV Administration Sets with Hand Pump (K140838)

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

Feature	Proposed Device IV Administration Sets	Predicate Device (K140838) IV Administration Sets with Hand Pump
Manufacturer	B. Braun Medical Inc.	B. Braun Medical Inc.
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
Indications for Use	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.	The IV Administration Sets with Hand Pump are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. When the hand pump component is activated, the device is intended to deliver only crystalloid and colloid resuscitative fluids. 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.
Mode of Fluid Delivery	Gravity Administration	Gravity and/or rapidly through Hand Pump Activation
Administration Set Components	Sets configured with various industry standard components including: insertion spike drip chamber tubing luer connections (connector/adaptor) manifold needleless luer access device stopcocks clamps check valve	Sets configured with various industry standard components including: insertion spike drip chamber tubing luer connections (connector/adaptor) manifold needleless luer access device stopcocks clamps check valve hand pump
Summary of nonclinical tests for determination of substantial equivalence	The following performance bench tests were performed: • Luer Compliance • Priming Test / Air Visualization • Flow rate and occlusion • Positive pressure test • Dynamic Tensile test • Static Tensile test	The following performance bench tests were performed: • Luer Compliance • Priming Test / Air Visualization • Flow rate and occlusion • Positive pressure test • Dynamic Tensile test
Fluid Contacting Materials	Externally communicating blood path indirect prolonged contact	Externally communicating blood path indirect prolonged contact
Materials and Biocompatibility	Materials meet biocompatibility requirements per ISO 10993-1: Cytotoxicity Sensitization Intracutaneous reactivity Systemic toxicity Hemolysis Rabbit pyrogen Characterization of leachables	Materials meet biocompatibility requirements per ISO 10993-1: Cytotoxicity Sensitization Intracutaneous reactivity Systemic toxicity Hemolysis Rabbit pyrogen Characterization of leachables
Sterilization	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}

Non Clinical Performance Testing

The following performance standards were utilized in evaluating the functionality of the IV Administration Sets. The performance bench tests conducted are listed under the applicable standard.

Standard

ISO 594-1:1986, "Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements"

ISO 594-2:1998, "Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings"

Tests - Luer Compliance

Standard

ISO 8536-4:2010/Amd. 1: 2013, "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed"

Tests - Flow Rate, Positive Pressure, Negative Pressure and Static Tensile

Standard

ISO 10993-1:2009, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Tests - Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Hemolysis, Material Mediated Rabbit Pyrogen and Characterization of Leachables

The following additional tests were also performed: Dynamic Tensile, Priming, Air Bubble Visualization and Low Pressure Occlusion.

A risk assessment was performed with no additional risks and no change to the risk profile identified. Non clinical testing performed on the predicate device was completed with the proposed IV Administration Sets to demonstrate equivalence. Results of testing show that the proposed devices meet the same performance specifications and are substantially equivalent to the predicate device. The fundamental technology of the proposed sets is unchanged when compared to the predicate device.

CONCLUSION

The results of performance and biocompatibility testing along with the same intended use, and similar indications for use and technological characteristics demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device.