March 3, 2022

B.Braun Medical Inc.
Tracy Larish
Sr. Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, Pennsylvania 18109

Re: K213778
Trade/Device Name: IV Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: November 24, 2021
Received: December 3, 2021

Dear Tracy Larish:

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)*
K213778

Device Name
IV Administration Set

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.

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K213778
510(k) SUMMARY

SUBMITTER INFORMATION:

Name:	B. Braun Medical Inc.
Address:	901 Marcon Boulevard Allentown, PA 18109-9341
Telephone Number:	610-266-0500, ext. 2966
Contact Person:	Tracy Larish, Sr. Regulatory Affairs Specialist
Telephone Number:	(610) 596-2941
Fax Number:	(610) 849-9286
Email:	tracy.larish@bbraunusa.com
Date Prepared:	February 3, 2021

DEVICE NAME:

Device Trade Name:	IV Administration Set
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular administration set, 21 CFR §880.5440: Class II, Product code FPA

PREDICATE DEVICES:

- K173361 IV Administration Set, B. Braun Medical Inc.

DEVICE DESCRIPTION

IV Administration Sets are gravity, 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), filter, and hand pump. IV Administration sets are configured to ensure the intended use of the device is met.

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.

TECHNOLOGICAL CHARACTERISTICS:

The IV Administration Set is substantially equivalent to the B. Braun Medical Inc. IV Administration Set (K173361). The predicate device used for comparison to the IV Administration Set was utilized to demonstrate the substantial equivalence in Indications for Use, intended use, and design between the proposed device and the predicate devices.

The IV Administration Set has the same intended use, the same principle of operation, the same fundamental scientific technology and Indications for Use as the predicate device. It comprised of similar component types and meet the same relevant performance specifications as the predicate devices.

The fundamental technology of the proposed set is unchanged when compared to the predicate device. The differences between the proposed IV Administration Set and predicate device are listed below. These differences do not raise new issues of safety and effectiveness.

- The Spin lock Luer connector with primestop cap has been modified to be a fixed male luer lock and the material of construction have been changed.
- The roller clamp design has been modified to include a docking location for the insertion spike and the materials of construction have been changed.
- An in-line filter was added to the set.

A table summarizing the comparison between the IV Administration Sets and the predicate devices is provided below:

	Proposed IV Administration Set (K213778)	**Predicate Device (K173361) IV Administration Set with HCO tubing**	**Differences**
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 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
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
Mode of Fluid Delivery	Gravity	Gravity	Same
Administration Set Components/ materials	Drip chamber PVC Insertion spike-ABS Roller Clamp-ABS Tubing- PVC w/ DEHT and HCO Luer connection- MABS/PP In line filters-MABS/ABS PPSU/PVP/PTFE	Drip chamber-PVC Insertion spike-ABS Roller clamp-ABS Tubing -PVC w/ DEHT and HCO Luer connections-MABS/PC Injection site-Acryllic/Polyisoprene Needleless Y-site – PC Back check valve- MABS	Design and material change to the roller clamp and luer connector. Addition of in-line filter. Biocompatibility and performance testing were performed to demonstrate substantial equivalence (see below).
Summary of nonclinical tests for determination of substantial equivalence	ISO 8536-4 Physical Requirements • Particulate • Leakage • Flow Rate • Tensile Strength • Closure-piercing device • Air-inlet device • Tubing • Drip chamber • Flow Regulator • Male Conical Fitting • Protective Caps ISO 8536-8 ISO 80369–7:2016 ISO 80369–20:2015 Internal Testing • Microbial Ingress • Particulate Testing per USP <788> • Stress Cracking • Roller Clamp function • Joint testing • Simulated use Testing • Lipid Compatibility	ISO 8536-4 Physical Requirements • Particulate • Leakage • Flow Rate • Tensile Strength • Closure-piercing device • Air-inlet device • Tubing • Drip chamber • Flow Regulator • Male Conical Fitting • Protective Caps	Additional tests performed to confirm substantial equivalence
Patient Contact category/ Duration	Externally Communicating, Blood Path Indirect prolonged exposure	Externally Communicating, Blood Path Indirect prolonged exposure	Same

	Proposed IV Administration Set (K213778)	**Predicate Device (K173361) IV Administration Set with HCO tubing**	**Differences**
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Same
Pyrogenicity	Pyrogenicity <0.5 EU/mL	Pyrogenicity <0.5 EU/mL	Same
Sterilization	Ethylene Oxide SAL 10-6	Ethylene Oxide SAL 10-6	Same

NONCLINICAL TESTING

Bench testing performed on IV Administration Sets to demonstrates that the device performs as intended. No clinical testing was performed as these devices does not require clinical studies to demonstrate substantial equivalence with the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 8536-4: "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed"
- ISO 8536-8: "Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus"
- ISO 10993-1: "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- ISO 10993-7 2nd Edition 2008-10-15Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]
- 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
- ISO 80369-20: "Small-bore connectors for liquids and gases in healthcare applications-Part 20:Common test methods

CONCLUSION:

Results of the functional and performance testing conducted on the proposed devices demonstrate that the IV Administration Set is equivalent to the predicate device. The differences, between subject device and predicate device, do not raise any new issues of safety and effectiveness. The subject IV Administration Set has demonstrated to be substantially equivalent to the predicate device.