June 26, 2018

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

Re: K173361
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: May 21, 2018
Received: May 22, 2018

Dear Nancy Skocypec:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.06.26 15:15:00 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173361

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K173361 510(k) SUMMARY

DATE:	June 26, 2018
SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 Contact: Nancy Skocypec Phone: (610) 596-2798 Fax: (610) 266-4962 E-mail: nancy.skocypec@bbraun.com
DEVICE NAME:	IV Administration Set
COMMON NAME:	IV Administration Set
CLASSIFICATION:	Class II, Product Code FPA, 21 CFR 880.5440 General Hospital
PREDICATE DEVICE:	U & U Intravascular Administration Set, U & U Medical Technology Co., Ltd., K151151, Class II, FPA, 21 CFR 880.5440 General Hospital

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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, needleless luer access device, injection site, check valve, tubing, clamp, and luer connection (connector, adaptor). IV Administration sets are configured to ensure the intended use of the device is met.

Indication 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
The IV Administration Sets are substantially equivalent to the predicate device, U&U IV Administration Sets cleared with K151151.

Technological Characteristics
The IV Administration Sets presented in this submission have similar 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 similar component types, and meet the same relevant performance specifications as the predicate devices. Both sets are comprised

of similar industry standard materials. The tubing material utilized with both sets is PVC. The proposed device tubing material contains hydrogenated castor oil within its formulation.

Successful completion of biocompatibility testing and chemical characterization testing per ISO 10993 confirmed that this difference in materials did not impact the biological or chemical safety of the IV Administration Sets. Additionally, performance testing was performed to ensure that this formulation did not impact the substantial equivalence of the device.

A table summarizing the comparison between the B. Braun IV Administration sets and the predicate device is provided below.

Feature	Proposed Device IV Administration Sets	Predicate Device (K151151) U & U Intravascular Administration Set
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 device is intended to administration fluids from a container into a patient's vascular system through a needle or catheter inserted into the vein.
Mode of Fluid Delivery	Gravity	Gravity
Materials	Tubing – PVC w/ DEHT and HCO Spike – ABS Back check valve - MABS Roller clamp - ABS Luer connections – MABS/PC Drip chamber – PVC Injection site – Acryllic/Polyisoprene Needleless Y-site - PC	Tubing – PVC Spike – ABS Back check valve – ABS Roller Clamp – ABS Male Lure Lock – ABS Drip Chamber – unknown Needleless Y-Site - unknown
Summary of nonclinical tests for determination of substantial equivalence	ISO 8536-4 Physical Requirements • Particulate ○ contamination index ≤ 90 • Leakage • Flow Rate • Tensile Strength • Closure-piercing device • Air-inlet device • Tubing • Drip chamber • Flow Regulator • Male Conical Fitting • Protective Caps	ISO 8536-4 Physical Requirements • Particulate • Leakage • Flow rate • Tensile strength • Closure-piercing device • Air-inlet device • Tubing • Drip chamber

Feature	Proposed Device IV Administration Sets	Predicate Device (K151151) U & U Intravascular Administration Set
Patient Contact category / duration	Externally communicating blood path indirect prolonged contact	unknown
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Pyrogenicity	<0.5 EU/mL	< 0.5EU
Sterilization	Ethylene Oxide, SAL 10^{-6}	unknown

The fundamental technology of the proposed device is equivalent to the predicate device. The differences between the subject device and predicate device do not raise different questions of safety and effectiveness.

Performance Testing

Non-clinical performance testing was completed with the proposed IV Administration Sets to demonstrate that the sets perform as intended. The test results demonstrated that the proposed device complies with the following standards:

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

ISO 80369-7:2016, "Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications"

ISO 10993-1:2009(R)2013, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
Biocompatibility testing included cytotoxicity, irritation, sensitization, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility testing

ISO 11135:2014, "Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"

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

- Tubing-Slide Clamp Compatibility
- Chemical resistance testing
- Occlusion
- Dynamic tensile strength
- Leakage – negative pressure test

Microbial ingress data for the needleless luer access devices and injection sites was referenced to the previously cleared 510(k)'s K031923, K931377, K083723, and K140311 for these components.

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 functional and performance testing conducted on the proposed device demonstrate that the IV Administration Sets performance 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 Sets has demonstrated to be substantially equivalent to the predicate device.