DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 6, 2016

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

Re: K153293
Trade/Device Name: Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 8, 2016
Received: March 9, 2016

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
Not yet known K153293

Device Name
Extension Sets

Indications for Use *(Describe)*

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. B. Braun Extension Sets may be used for any patient population.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

DATE: March 8, 2016

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

Contact: Kimberly Smith, Regulatory Affairs Specialist
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DEVICE NAME: Extension Sets

COMMON OR USUAL NAME: IV Administration Set

CLASSIFICATION: Class II, Product Code FPA, 21 CFR §880.5440, Intravascular administration set

PREDICATE DEVICES: K083472 Medegen, Incorporated
K140831 CareFusion (formerly Medegen, Incorporated)
Class II, Product Code FPA, 21 CFR §880.5440

DESCRIPTION:

B. Braun Extension Sets are single use, disposable, add-on devices used for direct injection, intermittent infusion, continuous infusion or aspiration. In clinical practice, extension sets are connected to primary IV 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. An extension set attached to a catheter hub allows the clinician to perform syringe aspirations and injections away from the patient's catheter site.

Extension Sets are widely used in the clinical setting, are available in various lengths and dimensions, and may be comprised of various generic components that are broadly used throughout the industry. Various components such as stopcocks, clamps, injection sites, connectors, manifolds, filters and needleless connectors, previously cleared in 510(k)s, may be included on an Extension Set. B. Braun Extension Sets offer a range of lengths and a variety of tubing dimensions (ie: microbore, smallbore, standard bore) that provide flexibility in a variety of clinical settings. B. Braun Extension Sets are configured to ensure the intended use of the device is met.

B. Braun's optional stabilization component is a non-removable component that slides on the tubing and may be firmly positioned on the patient connector, secured at the discretion of the clinician at time of use. The optional stabilization component provides additional stabilization to intravascular catheters while firmly positioned on the patient connector of the Extension Set. The optional stabilization component supports the patient connector of the extension set, reducing its contact with the skin. The geometrical design of the stabilization component supports the patient connector maintaining the catheter insertion angle, minimizing the catheter movement in the vessel and the potential for catheter kinking at the insertion site.

Select B. Braun Extension Sets that may be used with a power injector at a maximum pressure of 400 psi and a maximum flow rate of 15mL/second.

B. Braun Extension Sets may be used for any patient population.

Extension Sets comprised of a female luer adapter, extension tubing, slide clamp, stabilization component and a male luer adapter with cap are included in this premarket notification. The following Extension Set configurations are subject of this submission.

- Smallbore Extension Set with stabilization component, Spin-Lock connector, removable slide clamp
- Standard Bore Extension Set with stabilization component, Spin-Lock connector, slide clamp
- Extension Set with stabilization component, Spin-Lock connector, slide clamp

INTENDED USE:

B. Braun Extension Sets are intended for direct injection, intermittent infusion, continuous infusion or aspiration.

INDICATIONS FOR USE:

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. B. Braun Extension Sets may be used for any patient population.

SUBSTANTIAL EQUIVALENCE:

Item	Proposed Device: Extension Sets	Predicate Device: CareFusion (formerly Medegen Incorporated) K083472, Publically Available Information	Predicate Device: CareFusion (formerly Medegen Incorporated) K140831, Publically Available Information
510(k) Number	K153293	K083472	K140831
FDA Regulation Number, Regulation Name, Class, and Product Code	21 CFR 880.5440 Intravascular Administration Set Class II FPA	21 CFR 880.5440 Intravascular Administration Set Class II FPA	21 CFR 880.5440 Intravascular Administration Set Class II FPA
Intended Use	Intended for direct injection, intermittent infusion, continuous infusion or aspiration.	Intended for direct injection, intermittent infusion, continuous infusion or aspiration.	Intended for direct injection, intermittent infusion, continuous infusion or aspiration.
Indications	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 at a maximum flow rate of 15 mL per second. B. Braun's optional stabilization component on an extension set is intended to provide stability to the patient connector, which is attached to an intravascular catheter. B. Braun Extension Sets may be used for any patient population.	The Medegen Pressure Rated Extension Sets are intended for use in today's growing professional healthcare environment, including healthcare facilities, home care and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products. The Medegen Pressure Rated Extension Sets allow the user to add medication into the primary line without the use of a needle. The Medegen Pressure Extension Sets may also be used with low-pressure power injectors rated up to 325 psi.	Pressure Rated: The MaxZero multi fuse extension set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second. Non Pressure Rated: The MaxZero multi fuse extension set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.
Description	B. Braun Extension Sets are single use, disposable, add-on devices used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products. Select B. Braun Extension Sets may be used with power	Extension Sets are intended for single patient use, for infusion systems for the delivery of fluids, medications, blood and blood products. The Medegen Pressure Rated Extension Sets allow the user to add medication into the primary line without the use of a needle. The Medegen Pressure	Extension Sets are intended for single patient use, including pediatrics and immuno-compromised patients, for direct injection, intermittent infusion continuous infusion or aspiration of drugs, blood and fluids. Pressure rated sets may be used with power injector procedures to a maximum pressure of 325 psi

	injector procedures to a maximum pressure of 400 psi and at a maximum flow rate of 15mL per second. B. Braun Extension Sets may be comprised of various generic components that are broadly used in clinical practice such as stopcocks, clamps, injection sites, connectors, manifolds, filters and needleless connectors. B. Braun Extension Sets also contain an optional stabilization device.	Extension Sets may also be used with low-pressure power injectors rated up to 325 psi. Configurations are available with needleless connectors, split septum ports, filters, stopcocks, manifolds and/or T-connectors.	at a flow rate of 10mL per second. Configurations are available with needleless connectors, split septum ports, filters, stopcocks, manifolds and/or T-connectors.
Device Components	Tubing, Luer, Slide Clamp, Stabilization Component, Spin-Lock Connector (also known as patient connector, male luer adapter)	Tubing, Luer, Check Valve, Slide Clamp, Needleless Connector, Male Spin lock connector	Tubing, Luer, Check Valve, Slide Clamp, Needleless Connector, Male Spin lock connector

Technological Characteristics

The B. Braun Extension sets have the following similarities to the predicate devices:

- Same Intended Use
- Indications for Use
- Extension Set design
- Principle of operation
- May be used with power injection procedures

The following differences exist between the subject and predicate devices:

- the subject device includes a stabilization component
- the subject device may be used may be used with power injector procedures to a maximum pressure of 400 psi and a maximum flow rate of 15 mL per second
- the subject device may be used with a needleless connector whereas the predicate device has a needleless connector incorporated on the set

These differences in the indications for use statement for the subject device and predicate devices do not alter the intended use of the subject device. Both the subject and predicate devices have the same intended use for direct injection, intermittent infusion, continuous infusion or aspiration.

Non-Clinical Data - Performance Testing

B. Braun performed design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predicate devices. All test results met their acceptance criteria and support that B. Braun Extension sets are appropriately designed for their intended use.

The following performance standards were utilized in evaluating the functionality of the Extension Sets:

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"

ISO 1135-4:2012: "Transfusion equipment for medical use – Part 4: Transfusion sets for single use"

ISO 8536-4:2010, "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed"

ISO 8536-8:2015, "Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus"

ISO 11135-1:2007, "Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"

Successful functional performance testing was completed with the proposed Extension Sets with a stabilization component to demonstrate that the sets perform as intended. The following performance data were provided in support of the substantial equivalence determination:

- Stabilization Component Angular/Axial Stabilization/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

Biocompatibility

The materials of construction of the subject device were evaluated according to the provisions of ISO 10993-1:2009, "Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process". B. Braun applied component material testing as well as finished product testing to demonstrate the biocompatibility of the final device. B. Braun performed testing according to the following parts of the ISO 10993 standard.

ISO 10993-4:2002, "Biological evaluation of medical devices - part 4: Selection of tests for interactions with blood"

ISO 10993-5:2009, "Biological evaluation of medical devices - part 5: Tests for *in vitro* cytotoxicity"

ISO 10993-10:2010, "Biological evaluation of medical devices - Part 10: Test for irritation and delayed-type hypersensitivity"

ISO 10993-11:2006, "Biological evaluation of medical devices - Part 11: Test for systemic toxicity"

ISO 10993-17:2002, "Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances"

ISO 10993-18:2005,"Biological evaluation of medical devices - Part 18: Chemical characterization of materials"

CONCLUSION:

Results of functional performance and biocompatibility testing conducted with the proposed device along with the same intended use, similarities in indications for use and technological characteristics demonstrate that the B. Braun Extension Sets are substantially equivalent to the predicate device.