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

July 24, 2015

B. Braun Medical Inc.
Ms. Angela J. Caravella
Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, PA 18109

Re: K143082
Trade/Device Name: IV Administration Sets with 200um Blood Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 18, 2015
Received: June 22, 2015

Dear Ms. 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. 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,

Tina Kiang -S

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 below.

510(k) Number *(if known)*

K143082

Device Name
IV Administration Sets with 200µm Blood Filter

Indications for Use *(Describe)*

The IV Administration Sets with 200µm Blood Filter are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system. When the hand pump component is activated, the device is intended to deliver blood, blood products and 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 the 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)

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)*

5. 510(k) SUMMARY K143082

DATE: July 23, 2015

SUBMITTER:

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610-266-0500

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DEVICE NAME: IV Administration Sets with 200µm Blood Filter

COMMON OR NAME: IV Administration Sets with 200µm Blood Filter

CLASSIFICATION: Class II, Product Code FPA, 880.5440

PREDICATE DEVICE: Hospira Infusion Blood Sets, Hospira Inc., K101677, Class II, FPA, 880.5440

REFERENCE DEVICE: Modified Blood Administration Sets, Baxter Healthcare Corporation, K993120, Class II, BRZ, 880.5440

DESCRIPTION:

The IV Administration Sets with 200µm Blood Filter are single use, disposable, intravenous administration sets used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system, rapidly through the use of a hand pump, or through gravity flow. The sets include tubing, a 60 cm^2 filter with a 200 micron pore size, bag spike, luer connector, roller clamp and slide clamp. The sets may be equipped with a manually activated hand pump, stopcocks, manifolds, and/or luer access devices.

INDICATIONS FOR USE:

The IV Administration Sets with 200µm Blood Filter are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system. When the hand pump component is activated, the device is intended to deliver blood, blood products and 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 the duration of therapy.

INTENDED USE:

The IV Administration Sets with 200µm Blood Filter are single use, disposable, intravenous administration sets with optional pressure pump used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system, rapidly through the use of the pressure pump and/or through gravity flow.

SUBSTANTIAL EQUIVALENCE:

The IV Administration Sets with 200µm Blood Filter are substantially equivalent to the Hospira Infusion Blood Sets (K101677) predicate device. Additionally, the Baxter Modified Blood Administration Sets (K993120) 510(k) are utilized as a reference 510(k) for this submission.

The proposed device has the same intended use, similar indications for use, and does not possess significantly different technological characteristics when compared to the predicate device since the IV Administration Sets with 200µm Blood Filter are comprised of similar components with a similar design. The IV Administration Sets with 200µm Blood Filter, as well as the predicate are provided as sterile, individually packaged for single use.

The Baxter Modified Blood Administration Sets (K993120) 510(k) was utilized as a reference device to demonstrate similarities in the mechanical hemolysis response between the proposed IV Administration Sets with 200µm Blood Filter device and a commercially marketed blood set.

The proposed device has similarly worded indications for use as the predicate device. The predicate Hospira Infusion Blood Sets are indicated for the delivery of fluids including, but not limited to blood and blood products from a container into a patient’s vascular system. The proposed device is indicated for the delivery of blood, blood products, and IV fluids from a container to a patient’s vascular system. While the exact verbiage of the indications for use are not identical, they do represent the same indications for use – delivery of fluids, including blood, blood products, and IV fluids from a container to a patient’s vascular system – and the verbiage differences are not critical to the intended use of the device. The difference in verbiage used to describe the same indications for use does not affect the safety and effectiveness of the proposed device.

Comparison of Technological Characteristics with the Predicate Device

The IV Administration Sets with 200µm Blood Filter possess the same technological characteristics as the predicate Hospira Infusion Blood Set cleared under 510(k) K101677.

A table summarizing the comparison between the IV Administration Sets with 200 µm Blood Filter to the predicate device is provided below:

Comparison of Proposed Device with Predicate Device		
	Proposed Device **IV Administration Sets with 200µm Blood Filter**	**Predicate Device** (K101677) Hospira Infusion Blood Sets
Indications for Use	The IV Administration Sets with 200µm Blood Filter are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system.	Hospira Administration sets are intended for the delivery of fluids including but not limited to blood and blood products from a container into a patients vascular system.
Set method of administration	Gravity or Hand Pump Activation	Gravity or Hand Pump Activation
Hand Pump Design	Cylindrical shape with ball check valves	Cylindrical shape with ball check valves
Set contains an Injection Site / Luer Access Device?	Yes	Yes
Blood Filter Composition	Polyamide	Unknown
Blood Filter Pore Size	200µm	200µm
Blood Filter Surface Area	$60cm^2$	Unknown
Intended Use	Administration of blood, blood components, and IV fluids	Administration of blood, blood components, and fluids
Sterilization Method	Ethylene Oxide	Radiation

The technological differences that exist between the proposed and predicate devices were evaluated to confirm they were as safe and as effective as the predicate device. Both the proposed and predicate devices utilized the acceptance criteria for Blood Filter Surface Area and Blood Filter Composition that is identified in the ISO 1135-4 standard. Biocompatibility testing further confirmed the safety of the material of the blood filter in accordance with ISO 10993-1.

Performance Testing

The following performance standards were utilized in evaluating the functionality of the IV Administration Sets with 200µm Blood Filter:

ISO 1135-4:2010 and 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"

Functional performance testing was completed with the proposed IV Administration Sets with 200µm Blood Filter to demonstrate that the sets perform as intended.

The following performance data were provided in support of the substantial equivalence determination:

- Ability to prime and visualize air in set
- Flow rate under gravity
- Flow rate with activation of hand pump
- Drop former function
- Ability to withstand negative (vacuum) and positive pressures
- Associate device with pressure cuff on an IV bag attached to the set (pressure and leakage)
- Joint tensile strength
- Blood Filter Mesh Minimum Surface Area
- Blood Filter Mesh Efficiency Test
- Mechanical Hemolysis Performance Comparison between Proposed Device and the Reference Device

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Biocompatibility

The materials of construction of a fully assembled IV Administration Sets with 200µm Blood Filter were tested according to ISO 10993-1:2009.

The biocompatibility testing that was performed on the full device includes:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- Hemolysis
- Coagulation/Platelets
- Rabbit Pyrogen

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 the same technological characteristics demonstrate that the IV Administration Sets with 200µm Blood Filter are substantially equivalent to the predicate device and are as safe and as effective as the predicate device for their intended use.
