DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 28, 2015

Baxter Healthcare Corporation
Mr. Gary Chumbimune
Manager, Regulatory Affairs
32650 N Wilson Road
Round Lake, Illinois 60073

Re: K153158
Trade/Device Name: Solution Administration Sets with 0.2 Micron Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 2, 2015
Received: December 3, 2015

Dear Mr. Chumbimune:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 below.

510(k) Number *(if known)*

K153158

Device Name
Solution Administration Sets with 0.2 Micron Filter

Indications for Use *(Describe)*
For the retention of microorganisms and removal of air and particulate matter from infusion fluids.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary K153158

October 30, 2015

OWNER:

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CONTACT PERSON:

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IDENTIFICATION OF THE DEVICE:

Common Name: Intravascular Administration Set
Trade Name or Proprietary Name: Solution Administration Sets with 0.2 Micron Filter
Classification Panel: 80 General Hospital
Classification: Set, Administration, Intravascular
(21 CFR 880.5440)
Class: Class II
Product Code: FPA

Table 1. Product Codes for Solution Administration Sets with 0.2 Micron Filter

Code Number	Name
2C6572	INTERLINK System CONTINU-FLO Solution Set
2H6480	INTERLINK System Non-DEHP Solution Set with DUO-VENT Spike
2H8671	CLEARLINK System Non-DEHP Extension Set
1C8363	Extension Set

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Solution Administration Sets with 0.22 Micron Filter	Baxter Healthcare Corporation	K964850	February 25, 1997

DESCRIPTION OF THE DEVICE:

The Solution Administration Sets with a 0.2 micron filter product line consists of sterile, non-pyrogenic, single use disposable devices used for the administration of fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. They are indicated for the retention of microorganisms and removal of air and particulate matter from infusion fluids. The filter consists of a 0.2 micron polyethersulfone (PES) solution membrane and 0.1 micron polyvinylidene fluoride air vent membrane enclosed in a copolyester housing. These devices were previously cleared under 510(k) premarket notification K964850 (cleared February 25, 1997)

The basis for this premarket notification is a modification to the 0.2 micron filter currently used in this product line. The modification consists of a change to the solution membrane material. The solution membrane material is changing from a hydrophilic polyethersulfone (PES) to another hydrophilic polyethersulfone (PES). The solution membrane currently used is no longer available and will be replaced with an equivalent material.

These modifications do not impact the intended use or the fundamental scientific technology of the devices. No other materials of construction are being introduced into these devices as part of this update. The product labels are also being updated to revise statements regarding latex and pump device references, add the indications for use statement of the device, and implement other modifications to comply with Baxter's labeling standards.

INDICATIONS FOR USE:

For the retention of microorganisms and removal of air and particulate matter from infusion fluids.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices have equivalent technological characteristics as Baxter's currently legally marketed devices cleared under 510(k) premarket notification K964850 (cleared on February 25, 1997). The intended use, design and function of the proposed devices are equivalent to the predicate devices.

DEVICE COMPARISON TABLE:

Table 3 is a device comparison table outlining the differences between the current (predicate) devices and the proposed devices.

Table 3. Device Comparison

Features		Current Devices (Cleared under K964850)	Proposed Devices
Intended Use		For the retention of microorganisms and removal of air and particulate matter from infusion fluids.	Same
Indications for Use		For the retention of microorganisms and removal of air and particulate matter from infusion fluids.	Same
Sterile		Yes	Same
Non-Pyrogenic		Yes	Same
Single Use		Yes	Same
Materials			
Spike		Acrylonitrile Butadiene Styrene	Same
Blue Plug		Synthetic Polyisoprene	Same
Cannula		304 Stainless Steel	Same
Drip Chamber		Polyvinyl Chloride	Same
Check Valve		Polymethyl Methacrylate and Silicone Rubber	Same
0.2 Micron Filter	Housing	Copolyester	Same
	Solution Membrane	Polyethersulfone (PES)	Same
	Air Vent Membrane	Polyvinylidene (PVDF)	Same
Trilayer Tubing	Inner Layer	Linear Low Density Polyethylene	Same
	Middle Layer	Polyolefin Adhesive	Same
	Outer Layer	Polyvinyl Chloride	Same
Tubing		Polyvinyl Chloride	Same
Bushing		Polyvinyl Chloride	Same
Interlink Y-Site		Copolyester and Synthetic Polyisoprene	Same
Clearlink Y-Site		Polycarbonate and Silicone	Same
Male Luer Lock Connector		Acrylonitrile Butadiene Styrene	Same

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

Performance Data:

The following bench tests were conducted to evaluate the effect of the modification to the 0.2 micron filter:

- Air diffusion test
- Bubble point test
- Gravity flow rate test
- Flow rate test post sterile water conditioning
- Flow rate test post parenteral nutrition conditioning
- Bacterial retention test

All tests met the acceptance criteria.

Biocompatibility:

The basis for this premarket notification is a modification to the 0.2 micron filter solution membrane material. The solution membrane material is changing from a hydrophilic polyethersulfone (PES) to another hydrophilic polyethersulfone (PES). No other materials of construction are being introduced into these devices as part of this update.

Biocompatibility assessments were conducted in accordance with ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," for prolonged duration, external communicating device, indirect blood path, and FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993" as recommended in the IV Administration Sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]". The battery of testing included the following tests:

- Cytotoxicity
- Systemic Toxicity
- Intracutaneous

- Hemolysis
- Pyrogen
- Sensitization
- USP Physicochemical

All other materials found in these devices, that are the subject of this submission, have been previously cleared under Baxter's 510(k) premarket notifications K123868 (cleared January 8, 2013) and K150860 (cleared April 16, 2015).

CONCLUSION:

The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate devices that are currently marketed for the same intended use.