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

June 21, 2017

Baxter Healthcare Corporation
Mr. John Lamela
Regulatory Affairs Specialist
32650 North Wilson Road
Round Lake, Illinois 60073

Re: K161808
Trade/Device Name: Solution Set with 1.2 Micron Air Eliminating Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 19, 2017
Received: May 22, 2017

Dear Mr. Lamela:

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" (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 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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
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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)*
K161808

Device Name
Solution Set with 1.2 Micron Air Eliminating Filter

Indications for Use *(Describe)*

For administering fluids from container to a patient's vascular system through a vascular access device. Used for the removal of particulate matter and elimination of air from infusion fluids while administering. May be used with TPN solutions containing lipid emulsions.

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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510(k) Summary – K161808

June 19, 2017

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IDENTIFICATION OF THE DEVICE:

Common Name: Intravascular Administration Set
Trade Name: Solution Set with 1.2 Micron Air Eliminating Filter
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, Administration, Intravascular
Regulatory Class: Class II
Product Code: FPA

Table 1. Product Codes for Solution Sets with 1.2 Micron Air Eliminating Filter

Code Number	Name
2C1103	INTERLINK System Non-DEHP Extension Set with 1.2 Micron Downstream Filter
2H8603	CLEARLINK System Non-DEHP Extension Set
2H8486	CLEARLINK System Non-DEHP Solution Set
2R8486	CLEARLINK System Non-DEHP Solution Set

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Solution Set with 1.2 Micron Air Eliminating Filter	Baxter Healthcare Corporation	K952074	July 27, 1995

DESCRIPTION OF THE DEVICE:

The Solution Set with 1.2 Micron Air Eliminating Filter product line consists of single use disposable device for administering fluids from container to a patient's vascular system through a vascular access device. Used for the removal of particulate matter and elimination of air from infusion fluids while administering. The filter consists of a 1.2 micron filter consisting of polysulfone solution membrane and a Teflon air vent media enclosed in an acrylic housing and may be used with TPN solutions containing lipid emulsions. The 1.2 micron filter has a maximum pressure of 45 psi (2241 kPa). The Solution Set with 1.2 Micron Air Eliminating Filter was previously cleared under 510(k) premarket notification K952074 (cleared July 27, 1995).

The basis for this premarket notification is modifications to the Solution Set with 1.2 Micron Air Eliminating Filter product line. The modifications consists of the use of a Non-DEHP PVC tubing material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer to provide an alternate to the current Non-DEHP PVC tubing material, conversion to sterile packaging, addition of an expiration date, and updates to the labeling.

Table 3. Summary of Proposed Changes per Product Code

Code and Description	Change Summary
2C1103 – INTERLINK System Non-DEHP Extension Set with 1.2 Micron Downstream Filter	1. Label Changes 2. Packaging Change 3. Addition of Exp. Date
2H8603 - CLEARLINK System Non-DEHP Extension Set	1. Label Changes 2. Packaging Change 3. Addition of Exp. Date
2H8486 – CLEARLINK System Non-DEHP Solution Set	1. Label Changes 2. Packaging Change 3. Addition of Exp. Date
2R8486 - CLEARLINK System Non-DEHP Solution Set	1. Label Changes 2. Packaging Change 3. Addition of Exp. Date

Table 3. Summary of Proposed Changes per Product Code

Code and Description	Change Summary
	4. Use of Non-DEHP PVC Tubing Material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer

These modifications do not impact the intended use or the fundamental technology of the devices. The product labels are being updated to revise statements regarding latex and pump device references, add the indications for use statement that was previously cleared for this device (K952074 - cleared July 27, 1995), include expiration dating, change from "fluid path is sterile" to "sterile" (sterile packaging), and implement other modifications to comply with Baxter's labeling standards. Note: The indications for use statement from the previously cleared 510(k) was modified, per the FDAs recommendation, to include the description in 21 CFR 880.5440.

Table 4. Set Configuration Using Proposed Non-DEHP PVC Tubing Material

Device Description	Code Number
CLEARLINK System Non-DEHP Solution Set 	2R8486

Table 5. Set Configuration of Current Codes

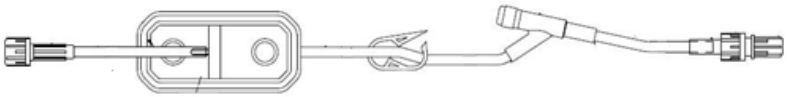
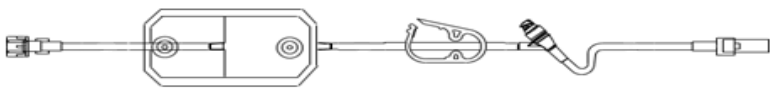
Device Description	Code Number
INTERLINK System Non-DEHP Extension Set with 1.2 Micron Downstream Filter 	2C1103
CLEARLINK System Non-DEHP Extension Set 	2H8603

Table 5. Set Configuration of Current Codes

Device Description	Code Number
CLEARLINK System Non-DEHP Solution Set 	2H8486

INDICATIONS FOR USE:

For administering fluids from container to a patient's vascular system through a vascular access device. Used for the removal of particulate matter and elimination of air from infusion fluids while administering. May be used with TPN solutions containing lipid emulsions.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices have equivalent technological characteristics as Baxter's current legally marketed device cleared under 510(k) premarket notification K952074 (cleared July 27, 1995).

DEVICE COMPARISON TABLE:

The comparison table below identifies similarities and differences of the proposed devices to the current legally marketed devices to which substantial equivalency is claimed.

Table 6. Device Comparison

Features		Predicate Device (K952074)	Proposed Devices	Assessment of Differences
Indications for use		The Baxter solution administration sets with 1.2 micron Supor IV-3 filter will be used for the removal of particulate matter and elimination of air from infusion fluids. The 1.2 micron filter sets may be used with TPN solutions containing lipid emulsions.	For administering fluids from a container to a patient's vascular system through a vascular access device. Used for the removal of particulate matter and elimination of air from infusion fluids while administering. May be used with TPN solutions containing lipid emulsions.	Alignment of language provided in 21 CFR 880.5440. In addition, reference to trade name (Supor IV-3) filter was removed since this name is no longer used (filter remains the same). These administrative changes have no impact to safety or effectiveness of the device.
Sterile		Yes	Same	No difference
Non-Pyrogenic		Yes	Same	No difference
Single Use		Yes	Same	No difference
Materials				
1.2 Micron Filter	Solution Membrane	Polysulfone	Same	No difference
	Air Vent Membrane	Teflon	Same	No difference
	Housing	Acrylic (Polymethyl Methacrylate)	Same	No difference
Spike		Acrylonitrile Butadiene Styrene	Same	No difference
Non-DEHP Drip Chamber		Polyvinyl Chloride	Same	No difference

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Table 6. Device Comparison

Features	Predicate Device (K952074)	Proposed Devices	Assessment of Differences
Female Luer Lock Connector	N/A	Blend of Copolyester and Hytrel	The predicate device does not have a female luer lock connector. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.
Non-DEHP Tubing[1] *(used on codes 2H8486, 2C1103, and 2H8603)*	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexl) Trimellitate	Same	No difference
Non-DEHP Tubing[2] *(used on code 2R8486)*	N/A	Material: Polyvinyl Chloride Plasticizer: Di (2-Ethylhexyl) terephthalate	This is the basis of this submission: modification consisting of the use of a Non-DEHP PVC tubing material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer. Design control activities have confirmed there is no impact to the safety or effectiveness for the new material.
Interlink Y-Site	N/A	Copolyester (Housing) Synthetic polyisoprene (Septum)	The predicate device does not have an Interlink Y-Site. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.
Clearlink Y-Site	N/A	Silicone Rubber (Gland) Polycarbonate (Housing, Housing Inlet, and Center Post)	The predicate device does not have a Clearlink Y-Site. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.

[1] Non-DEHP tubing material for current codes (2H8486, 2C1103, and 2H8603).
[2] Non-DEHP tubing material for proposed code (2R8486).

Table 6. Device Comparison

Features	Predicate Device (K952074)	Proposed Devices	Assessment of Differences
Two-Piece Male Luer Lock Connector	N/A	Acrylonitrile Butadiene Styrene	The predicate device does not have a Two-Piece Male Luer Lock Connector. Design control activities confirm the device meets the functional test requirements when used in accordance with the instructions for use.
One-Piece Male Luer Lock Connector	Acrylonitrile Butadiene Styrene	Same	No difference

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 (Table 7) were conducted to evaluate the effect of using a proposed Non-DEHP PVC tubing material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer. All evaluations were performed on the product code set configuration (Code: 2R8486) that is using the proposed Non-DEHP PVC tubing material.

Table 7. Performance Testing Summary

Test	Acceptance Criteria
Solvent Bond Tensile Strength Test	Per Baxter Test Method.
Solvent Bond Air Pressure Test	Per Baxter Test Method.
Continuous Bubble Test *(Pump Compatibility Test)*	Per Baxter Test Method.
Accumulated Bubble Test *(Pump Compatibility Test)*	Per Baxter Test Method.
Slide Clamp Shut-Off Test	Per Baxter Test Method.
Slide Clamp Shut-Off Test-Post 24 Hour	Per Baxter Test Method.
Slide Clamp 7 Day Subsystem and Tubing Damage Test	Per Baxter Test Method.
Slide Clamp Flow Stability Test	Per Baxter Test Method.
Slide Clamp Tug Stability Test	Per Baxter Test Method.

Table 7. Performance Testing Summary

Test	Acceptance Criteria
Upstream Occlusion Test *(Pump Compatibility Test)*	Per Baxter Test Method.
Downstream Occlusion Test *(Pump Compatibility Test)*	Per Baxter Test Method.
Roller Clamp Force Test	Per Baxter Test Method.
Roller Clamp Shut-Off Test	Per Baxter Test Method.
Roller Clamp 7 Day Subsystem and Tubing Damage Test	Per Baxter Test Method.
Roller Clamp Flow Stability Test	Per Baxter Test Method.
Roller Clamp Tug Stability Test	Per Baxter Test Method.
Total Parenteral Nutrition (TPN) Resistance Test	Per Baxter Test Method.
Roller Clamp Flow Control Test	Per Baxter Test Method.
Administration Set Integrity Test After Maximum Fluid Delivery *(Pump Compatibility Test)*	Per Baxter Test Method.
Flow Rate Accuracy Test *(Pump Compatibility Test)*	Per Baxter Test Method.
ISO Luer Tests on Male Luer Lock Connectors	Per ISO Standard 594

Note: All pump testing performed with the Sigma Spectrum Pump.

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path, and Blue Book Memorandum G95-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as recommended in the IV Administration Sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]". The Biocompatibility Tests and the applicable standards are listed in Table 8.

Table 8. Biocompatibility Tests and Applicable Standards

Biocompatibility Test	Applicable Standard
In Vitro Cytotoxicity	ISO10993-5
Sensitization	ISO10993-10
Intracutaneous (Irritation) Reactivity Assay	ISO10993-10
Systemic Injection (AcuteToxicity)	ISO10993-11
Sub-Chronic Toxicity (Repeat Dose)	ISO10993-11

Table 8. Biocompatibility Tests and Applicable Standards

Biocompatibility Test	Applicable Standard
Material Mediated Pyrogen	ISO10993-11
Hemocompatibility (In Vitro Hemolysis)	ISO10993-4
USP Physiochemical tests	USP <661>

Based upon the results of this prolonged duration, external communicating, indirect blood path testing, the Solution Sets with 1.2 Micron Air Eliminating Filter have been shown to be biocompatible and appropriate for their intended use.

Sterility

The Solution Set with 1.2 Micron Air Eliminating Filter product line is sterilized with radiation. The Minimum Sterilizing Dose (MSD) required to provide a 10^{-6} Sterility Assurance Level (SAL) for this (sub) category was established and validated at the manufacturing facility using Method No. 1 as described in ISO 11137-2, "Sterilization of health care products- Radiation-Part 2: Establishing the Sterilization Dose."

These products are labeled "Sterile, Nonpyrogenic." Package Verification testing is based on Visual Inspection, ASTM F88 Seal Strength, and ASTM F2096 Bubble Leak.

Shelf Life

Baxter has provided aging testing to support a shelf-life claim of twenty-four (24) months.

CONCLUSION:

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