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

December 19, 2016

Baxter Healthcare Corporation
Ms. Tiffany Lin
Manager, Regulatory Affairs
32650 North Wilson Road
Round Lake, Illinois 60073

Re: K160007
Trade/Device Name: Paclitaxel Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 15, 2016
Received: November 16, 2016

Dear Ms. Lin:

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 yours,

Tina Kiang -S

Tina Kiang, Ph.D.
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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)*
K160007

Device Name
Paclitaxel Sets

Indications for Use *(Describe)*
To administer fluids with Baxter infusion pumps to a patient's vascular system from a container though a needle or catheter inserted into a vein, primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration.

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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Section 5 – 510(k) Summary

December 16, 2016

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Intravascular Administration Sets
Trade Name: Paclitaxel Sets
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA

Table 1. Code Number for Paclitaxel Sets

Code Number	Name
2C7557	Interlink System Vented Paclitaxel Set
2C7558	Interlink System Paclitaxel Set
2C8857	Clearlink System Vented Paclitaxel Set
2C8858	Clearlink System Paclitaxel Set

PREDICATE DEVICE:

Table 2. Predicate 510(k)

Device	Company	Predicate 510(k)	Clearance Date
Solution Administration Set	Baxter Healthcare	K981792	August 17, 1998

REFERENCE DEVICES:

Table 3. Reference 510(k)s

Device	Company	Reference 510(k)	Clearance Date
Nitroglycerin Sets with DUO-VENT Spike	Baxter Healthcare	K150860	April 16, 2015
Solution Administration Sets with 0.2 Micron Filter	Baxter Healthcare	K153158	December 28, 2015

DESCRIPTION OF THE DEVICE:

The Paclitaxel Sets product line consists of single use disposable devices intended for the administration of fluids from a container into the patient's vascular system through a vascular device, primarily for solutions containing the chemotherapeutic drug paclitaxel. These devices are the same as the current marketed devices, which were previously cleared under 510(k) premarket notification K981792 (cleared August 17, 1998).

The sets are each comprised of a non-DEHP drip chamber with a spike, 0.2 micron filter, non-DEHP polyvinyl chloride tubing pump segment, polyethylene (PE)-lined trilayer tubing, and a luer lock. On all sets there is a fixtured slide clamp and an on-off roller clamp. Configurations of these sets differ in overall length, type of injection site (Interlink or Clearlink), and type of spike (vented or non-vented).

The basis for this premarket notification is a change to the PE-lined trilayer tubing and the 0.2 micron filter currently used in this product line. The inner layer material of the trilayer tubing is changing from Low Density Polyethylene to Linear Low Density Polyethylene. The solution membrane material of the 0.2 micron filter is changing from a hydrophilic polyethersulfone (PES) to another equivalent hydrophilic PES. All changes have been previously cleared under 510(k) premarket notifications for other Baxter Intravascular (IV) Administration Sets.

These changes do not impact the intended use or the fundamental scientific technology of the device. No other materials of construction are being introduced into this device 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 changes to comply with Baxter's labeling standards.

INDICATIONS FOR USE:

To administer fluids with Baxter infusion pumps to a patient's vascular system from a container though a needle or catheter inserted into a vein, primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are equivalent to Baxter's currently legally marketed devices cleared under 510(k) premarket notification K981792 (cleared August 17, 1998). The modifications consist of a changes to the PE-lined trilayer tubing and 0.2 micron filter, which have been previously cleared under 510(k) premarket notifications K150860 (cleared April 16, 2015) and K153158 (cleared December 28, 2015), respectively. The intended use, basic design, and function for the proposed device are equivalent to the predicate device. Table 4 is a device comparison table outlining the differences between the current (predicate) device and the proposed device.

Table 4. Device Comparison

Features	Current Device (Cleared under K981792)	Proposed Device
Intended Use	For the administration of fluids from a container into the patient's vascular system through a vascular device.	Same
Indications for use	To administer fluids to a patient's vascular system from a container through a needle or catheter inserted into a vein. The proposed solution set will be primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration with Baxter Flo-Gard® (6200 and 6300 series) and Colleague™ volumetric infusion pumps.	To administer fluids with Baxter infusion pumps to a patient's vascular system from a container though a needle or catheter inserted into a vein, primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration.[a]

Table 4. Device Comparison

Features	Current Device (Cleared under K981792)	Proposed Device
Sterile	Yes	Same
Non-Pyrogenic	Yes	Same
Single Use	Yes	Same
Materials		
Spike	Acrylonitrile Butadiene Styrene	Same
Drip Chamber	Polyvinyl Chloride	Same
Interlink Y-Site	Copolyester and Synthetic Polyisoprene	Same
Clearlink Y-Site	Polycarbonate and Silicone	Same
Minidrip Adapter	Synthetic Polyisoprene and Stainless Steel	Same
Trilayer Tubing	Polyvinyl Chloride, Polyolefin and Low Density Polyethylene	Polyvinyl Chloride, Polyolefin and Linear Low Density Polyethylene[b]
Tubing	Polyvinyl Chloride	Same
0.2 Micron Filter	Copolyester, Polyethersulfone (Millipore) and Polyvinylidiene Fluoride	Copolyester, Polyethersulfone (Membrana) and Polyvinylidiene Fluoride[c]
Male Luer Lock Connector	Acrylonitrile Butadiene Styrene	Same

[a.] The indications for use are being clarified to remove brand names of infusion pumps to align with current market terminology. This does not alter the intended use of the device.

[b.] Materials previously cleared under 510(k) premarket notification K150860 on April 16, 2015.

[c.] Materials previously cleared under 510(k) premarket notification K153158 on December 28, 2015.

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 modifications on the functional performance of the Paclitaxel Sets.

Table 5. Performance Testing Summary

Test	Acceptance Criteria
Clear Passage Test	Per Baxter test method.

Table 5. Performance Testing Summary

Test	Acceptance Criteria
Roller Clamp Force Test	Per Baxter test method.
Roller Clamp Shut-Off Test	Per Baxter test method.
Roller Clamp Tubing Leak Test	Per Baxter test method.
Solvent Bond Tensile Strength Test	Per Baxter test method.
Solvent Bond Air Pressure Test	Per Baxter test method.
Air Diffusion Test	Per Baxter test method.
Bubble Point Test	Per Baxter test method.
Gravity Flow Rate Test	Per Baxter test method.
Flow Rate Test Post Sterile Water Conditioning	Per Baxter test method.
Flow Rate Test Post Parenteral Nutrition Conditioning	Per Baxter test method.
Bacterial Retention Test	Per Baxter test method.
Upstream/Downstream Occlusion Test (with Baxter pumps: FLO-GARD and SIGMA Spectrum)	Per Baxter test method.
Drug Compatibility Test (Paclitaxel Concentration)	Equivalence to predicate device.
Drug Compatibility Test (pH)	Equivalence to predicate device.
Drug Compatibility Test (Color)	Equivalence to predicate device.
Drug Compatibility Test (Visual Inspection)	Equivalence to predicate device.

Biocompatibility:

Biocompatibility assessments were conducted in accordance with ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," to the category of prolonged duration, external communicating device, indirect blood path as recognized by FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993 and as recommended by the FDA Guidance Document issued July 11, 2008 "Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)]." The battery of testing included the following tests:

- Cytotoxicity (per ISO 10993-5)
- Systemic Toxicity (Acute and Sub-chronic) (per ISO 10993-11)
- Irritation/Intracutaneous Reactivity (per ISO 10993-10)
- Sensitization (per ISO 10993-10)
- Hemocompatibility (In Vitro Hemolysis) (per ISO 10993-4)

- Material Mediated Pyrogen (per ISO 10993-11)
- USP Physiochemical (per USP <661>)

Sterility:

The Paclitaxel Sets are sterilized with gamma 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 facilities to be within 14.2 – 25.0 kGy. Radiation sterilization validation and routine control at Baxter Healthcare Corporation is in compliance with ANSI/AAMI/ISO 11137-2.

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 tests to support a shelf-life claim of eighteen (18) months.

CONCLUSION:

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