DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 22, 2017

Baxter Healthcare Corporation
Jill Laack
Regulatory Affairs Specialist
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K172544
Trade/Device Name: Non-DEHP IV Fat Emulsion Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 21, 2017
Received: August 23, 2017

Dear Jill Laack:

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 (DICE) 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 (DICE) 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,

Tina Kiang, Ph.D.
Acting 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)*

K172544

Device Name
Non-DEHP IV Fat Emulsion Administration Sets

Indications for Use *(Describe)*
Indicated for use when low plasticizer solubility is desired (e.g., for administration of high lipid content solutions such as parenteral fat emulsion).

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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K172544

Section 5. 510(k) Summary

September 22, 2017

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IDENTIFICATION OF THE DEVICE:

Common Name: Intravascular Administration Sets
Trade Name: Non-DEHP IV Fat Emulsion Administration Sets
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.Device Model Code(s) Non-DEHP IV Fat Emulsion Administration Sets

Code Number	Name
2C1145	Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 10 drops/mL
2C1146	Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 60 drops/mL
2R1145	Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 10 drops/mL
2R1146	Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 60 drops/mL

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Low Plasticizer Solubility PVC Administration Set	Travenol Laboratories, S.A.[1]	K791496	April 8, 1980

[1] Travenol Laboratories, S.A. became Baxter Healthcare Corporation in 1988

Table 3. Reference 510(k)

Device	Company	Reference 510(k)	Clearance Date
Solution Set With 1.2 Micron Air Eliminating Filter	Baxter Healthcare Corporation	K161808	June 21, 2017

DESCRIPTION OF THE DEVICE:

The Non-DEHP IV Fat Emulsion Administration 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 needle or catheter inserted into a vein. The Non-DEHP IV Fat Emulsion Administration Sets are indicated for use when low plasticizer solubility is desired (e.g., for administration of high lipid content solutions such as parenteral fat emulsion). These sets are comprised of a drip chamber with a non-vented spike, non-DEHP polyvinyl chloride (PVC) tubing, and a two piece Luer lock. On all sets there is a fixture slide clamp and a regulating roller clamp. Configurations of these sets differ in drip chamber (60 drops/mL or 10 drops/mL). These devices are nonpyrogenic, sterile and can be used for gravity or pump infusion of I.V. fluids using Sigma Spectrum and other Baxter Infusion Pumps. The Non-DEHP IV Fat Emulsion Administration Sets were previously cleared on April 8, 1980 under 510(k) premarket notification "Low Plasticizer Solubility PVC Administration Sets" (K791496).

The basis for this premarket notification is modifications to the Non-DEHP IV Fat Emulsion Administration Sets product line. The modifications consist of the use of a Non-DEHP PVC tubing material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer, conversion to sterile packaging, and the addition of an expiration date. The proposed Non-DEHP PVC tubing material is currently used in Baxter's Solution Sets with 1.2 Micron Air Eliminating Filter and has been previously cleared under 510(k) premarket notification K161808 (cleared June 21, 2017).

The product labels are being updated to include compatible infusion pump device references, the addition of the indications for use statement, the addition of a latex statement, the addition of an expiration date, a change to the sterility claim, and to implement other clarifying information and modifications to comply with Baxter's labeling standards and other labeling enhancements.

See Table 4 for a summary of the proposed changes to the codes that are part of this premarket notification.

Table 4. Summary of Proposed Changes per Device Model Code

Code and Description	Change Summary
2C1145 - Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 10 drops/mL	1. Label Changes 2. Conversion to sterile packaging 3. Addition of Expiration Date
2C1146 - Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 60 drops/mL	1. Label Changes 2. Conversion to sterile packaging 3. Addition of Expiration Date
2R1145 - Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 10 drops/mL	1. Label Changes 2. Conversion to sterile packaging 3. Addition of Expiration Date 4. Use of Non-DEHP PVC Tubing Material that uses Di (2-Ethylhexyl) terephthalate as a plasticizer
2R1146 - Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 60 drops/mL	1. Label Changes 2. Conversion to sterile packaging 3. Addition of Expiration Date 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.

See Table 5 for the subject device model code set configuration that will utilize the proposed Non-DEHP PVC tubing material. Table 6 contains the remaining subject device model code set configurations that are part of this premarket notification.

Table 5. Set Configuration Using Proposed Non-DEHP PVC Tubing Material

Non-DEHP IV Fat Emulsion Administration Set 86" (2.2 m) Approximately 10 drops/mL	2R1145

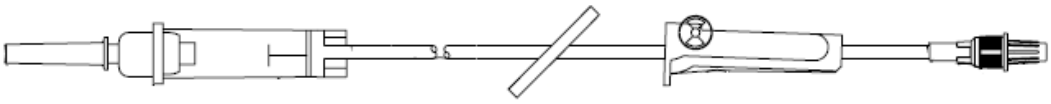
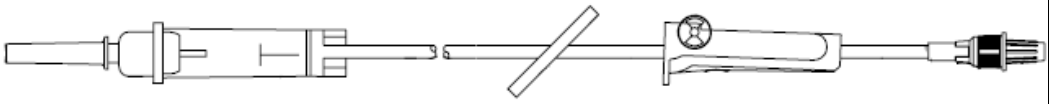
	
Non-DEHP IV Fat Emulsion Administration Set 86” (2.2 m) Approximately 60 drops/mL 	2R1146

Table 6. Set Configuration of Current Codes

Device Description	Code Number
Non-DEHP IV Fat Emulsion Administration Set 86” (2.2 m) Approximately 10 drops/mL 	2C1145
Non-DEHP IV Fat Emulsion Administration Set 86” (2.2 m) Approximately 60 drops/mL 	2C1146

INDICATIONS FOR USE:

Indicated for use when low plasticizer solubility is desired (e.g., for administration of high lipid content solutions such as parenteral fat emulsion).

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 K791496 (cleared April 8, 1980).

DEVICE COMPARISON TABLE:

Table 7 provides a comparison of the (predicate) device and the proposed devices. This comparison identifies similarities and differences of the proposed devices to the current legally marketed devices to which substantial equivalency is claimed.

Table 7. Device Comparison

Features	Predicate Device (Cleared under K791496)	Proposed Devices (2C1145, 2C1146, 2R1145, 2R1146)	Assessment of Differences
Indications for use	The IV Fat Emulsion Administration Sets are indicated for use when low plasticizer solubility is desired (e.g., for administration of high lipid content solutions such as parenteral fat emulsion).	The IV Fat Emulsion Administration Sets are indicated for use when low plasticizer solubility is desired (e.g., for administration of high lipid content solutions such as parenteral fat emulsion).	Same
Sterile	Yes	Yes	Same
Non-Pyrogenic	Yes	Yes	Same
Single Use	Yes	Yes	Same
Pump Compatibility	Not identified in submission	Yes, compatible with SIGMA Spectrum and other Baxter infusion pumps.	Pump compatibility was not identified in the original submission for the Predicate Device. Proposed codes have been tested for pump compatibility.
Materials			
Non-vented Spike	Not identified in submission	Acrylonitrile Butadiene Styrene	Materials were not identified in the original submission for the Predicate Device. The material has been previously cleared for the same intended use. All materials that are currently used have gone through design control activities which confirmed there was no impact to the safety or effectiveness of the device due to any changes of material.

Features	Predicate Device (Cleared under K791496)	Proposed Devices (2C1145, 2C1146, 2R1145, 2R1146)	Assessment of Differences
Drip Chamber	Not identified in submission	Polyvinyl Chloride	Materials were not identified in the original submission for the Predicate Device. The material has been previously cleared for the same intended use. All materials that are currently used have gone through design control activities which confirmed there was no impact to the safety or effectiveness of the device due to any changes of material.
Non-DEHP Tubing	Not identified in submission	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexl) Trimellitate (TOTM) (For codes 2C1145, 2C1146) Plasticizer: Di (2-Ethylhexl) Terephthlalate (DEHT) (For codes 2R1145, 2R1146)	Materials were not identified in the original submission for the Predicate Device. The material has been previously cleared for the same intended use. All materials that are currently used have gone through design control activities which confirmed there was no impact to the safety or effectiveness of the device due to any changes of material.
Cannula	Not identified in submission	Stainless Steel 304	Materials were not identified in the original submission for the Predicate Device. The material has been previously cleared for the same intended use. Materials that are currently used have gone through design control activities which confirmed there was no impact to the safety or effectiveness of the device due to any changes of material.

Features	Predicate Device (Cleared under K791496)	Proposed Devices (2C1145, 2C1146, 2R1145, 2R1146)	Assessment of Differences
Two Piece Luer Body	Not identified in submission	Acrylonitrile Butadiene Styrene	Materials were not identified in the original submission for the Predicate Device. The material has been previously cleared for the same intended use. All materials that are currently used have gone through design control activities which confirmed there was no impact to the safety or effectiveness of the device due to any changes of material.

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 the acceptance criteria, and support that the proposed devices are appropriately designed for their intended use. All testing was performed on the configuration of the devices presented in this premarket notification.

Performance Data:

The following bench tests (Table 8) were performed on subject device model code set configurations 2R1145 and 2R1146 (Table 5) in order to mitigate risks such as leaks, under/over infusion, failure to shut-off flow, interruption of therapy, air infused into patient, exposure to toxic materials, exposure to non-sterile product, exposure to endotoxins or pyrogens, set is not sterile and product not functioning during shelf-life. This testing that was performed for the proposed Non-DEHP PVC tubing material mitigated these risks so the devices are substantially equivalent to the predicate and can meet their intended use.

All testing described in this section was performed on codes that are listed in this submission or a worst case/representative sample. Worst case/representative samples were chosen because of having characteristics that are the same as the proposed device (e.g. –same components, same materials, same dimensions, and clamp/tubing interface).

Table 8. 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.
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.
Roller Clamp Flow Control Test	Per Baxter Test Method.
Administration Set Integrity Test After Maximum Fluid Delivery	Per Baxter Test Method
Visual Inspection For Structural Damage After 24 hours Exposure to Lipids	Per Baxter Test Method
Flow Rate Accuracy (Pump Compatibility Test)	Per Baxter Test Method
Non-DEHP Claim Verification	Per Baxter Test Method

Note: All pump compatibility testing was performed with the Sigma Spectrum Pump All tests met the acceptance criteria.

Biocompatibility:

The following cleared 510k submissions: K161808, K153158, and K130245 have identical materials and similar intended uses compared to this Non-DEHP I.V. Fat Emulsion Administration Sets premarket notification. All the devices in these submissions have similar risks that were adequately mitigated through testing to show the devices are substantially equivalent to the predicate and meet their intended use.

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 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.

Sterility

The Intravenous (IV) Fat Emulsion Administration Set 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 as described in ANSI/AAMI/ISO 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 performed aging testing to support a shelf-life claim of 2 (two) years.

CONCLUSION:

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