September 30, 2021

Baxter Healthcare Corporation
Jeffrey Thompson
Regulatory Affairs Specialist
25212 West Illinois Route 120
Round Lake, Illinois 60073

Re: K203609
Trade/Device Name: Intravascular Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 24, 2021
Received: August 31, 2021

Dear Jeffrey Thompson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203609

Device Name
Intravascular Administration Sets

Indications for Use *(Describe)*
For the administration of fluids from a container into the patient's vascular system through a vascular access device.

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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K203609 - 510(k) Summary

Preparation Date: **September 29, 2021**

OWNER: Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON: JEFFREY E. THOMPSON
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Telephone: (224) 270 3806
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IDENTIFICATION OF THE DEVICE:

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

PREDICATE DEVICE:

Table 1. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Solution Administration Sets	Baxter Healthcare Corporation	K112893	Oct 18, 2011

DESCRIPTION OF THE DEVICE:

The proposed devices consist of Intravascular Administration Sets. These devices include Basic, Secondary, and CONTINU-FLO solution sets. They are single use disposable, non-pyrogenic, sterile devices intended for the administration of fluids from a container into the patient's vascular system.

Basic Solution Sets:

The Basic solution sets consist of a spike tip protector, non-vented spike or vented spike, DEHP or non-DEHP drip chamber, non-DEHP tubing, DEHP tubing, slide clamp, regulating roller clamp, Clearlink Luer activated valve (LAV), Interlink injection site, two-piece male Luer lock and male Luer cap or one-piece male luer and male Luer cap. The Basic solution sets are used to administer solution directly from a container to a patient vascular system. These sets can be used with or without a baxter infusion pump.

Secondary Solution Sets:

The Secondary solution sets consist of a spike tip protector, non-vented spike or vented spike, DEHP or non-DEHP drip chamber, non-DEHP tubing, DEHP tubing, regulating roller clamp, On/Off roller clamps, two-piece male Luer lock and male Luer cap or one-piece male Luer and male Luer cap and hanger. The Secondary solution sets are used to administer solution directly from a container to a patient vascular system in a piggyback setup. Secondary solution sets are used in conjunction with CONTINU-FLO solution sets to administer intermittent fluids to the patient.

CONTINU-FLO Solution Sets:

The CONTINU-FLO solution sets consist of a spike tip protector, non-vented spike or vented spike, DEHP or non-DEHP drip chamber, non-DEHP tubing, DEHP tubing, check valve, slide clamp, regulating roller clamp, Clearlink Luer activated valve (LAV), Interlink injection site, two-piece male Luer lock and male Luer cap. The CONTINU-FLO solution sets are used to administer fluids from a container to a patient's vascular system. They can be used for gravity or pump infusion of I.V. fluids. CONTINU-FLO solution sets contain the Interlink Injection Site or Clearlink injection site that can be used for the administration of secondary medication. They also contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during the administration of secondary medication.

These sets were previously cleared under 510(k) premarket notification K961225 on June 21, 1996. The devices covered in this submission are substantially equivalent to the predicate devices, previously cleared under 510(k) premarket notification K112893 on October 18, 2011. The intended use and function of the proposed devices are equivalent to the predicate device.

Table 2. Representative IV Set Configurations

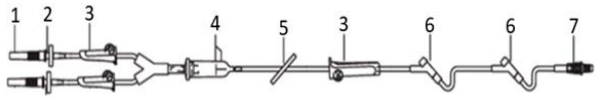
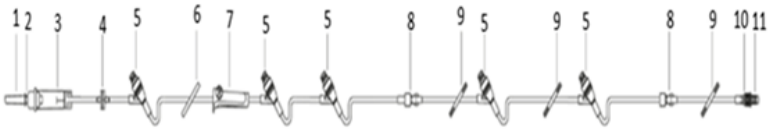
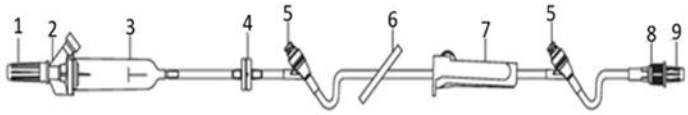
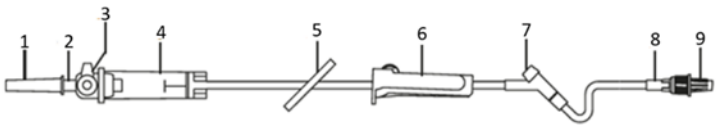
Code #	Device Description	
1C8581	Interlink System Y-Type Solution Set 79” (2.0 m) 	1. Spike Tip Protector 2. Spike 3. Roller Clamp 4. Drip Chamber 5. Slide Clamp 6. Interlink Y-Site 7. Male Luer
1C8722	Clearlink System Continu-Flo Solution Set 108” (2.7 m) Extension Set 20” (50cm) 3.3 mL Extension Set 5.5” (14cm) 0.74 mL 	1. Spike Tip Protector 2. Spike 3. Drip Chamber 4. Check Valve 5. Clearlink Y-Site 6. Pump Compatible Slide Clamp 7. Roller Clamp 8. In Line Connection 9. Slide Clamp 10. Male Luer 11. Male Luer Cap
2C8548	Clearlink System Vented Continu-Flo Solution Set 104” (2.6 m) 	1. Spike Tip Protector 2. Spike 3. Drip Chamber 4. Check Valve 5. Clearlink Y-Site 6. Pump Compatible Slide Clamp 7. Roller Clamp 8. Male Luer 9. Male Luer Cap
2C6419	Interlink System Solution Set with Duo-Vent Spike, 92” (2.3m) 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Pump Compatible Slide Clamp 6. Roller Clamp 7. Interlink Y-Site 8. Male Luer 9. Male Luer Cap

Table 2. Representative IV Set Configurations

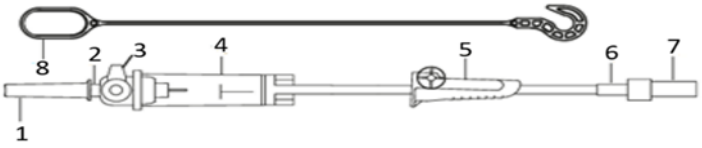
Code #	Device Description	
2H7463	Clearlink System Non-DEHP Secondary Medication Set with Duo-Vent Spike 37" (93 cm) 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Roller Clamp 6. Male Luer 7. Male Luer Cap 8. Hanger

Table 3. Indications For Use

Characteristic	**Predicate Device** Solution Administration Sets (K112893)	**Subject Device** Intravascular Administration Sets (K203609)
Indications for Use	For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to the standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluid.	For the administration of fluids from a container into the patient's vascular system through a vascular access device.

Discussion of Differences in Indications for Use Statement:

There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are substantially equivalent to the predicate devices, previously cleared under 510(k) premarket notification K112893 on October 18, 2011. The intended use and function of the proposed devices are equivalent to the predicate devices.

Table 4 is a device comparison table outlining the differences between the predicate and proposed devices.

Table 4. Device Comparison

Technological Characteristics	Predicate Device Device Name: K112893	Proposed Devices Device Name: K203609	Assessment of Differences
Indication for Use	For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to the standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluid.	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Different - See Comment #1 below.
Sterile	Yes	Same	No Differences
Non-Pyrogenic	Yes	Same	No Differences
Single Use	Yes	Same	No Differences
Length	6"(15.2 cm) – 100" (254 cm)	69" (175.26 cm)- 133.5" (339.09 cm)	Different - See Comment #2 below.
Priming Volume	0.46 mL – 15.3 mL	6.1 mL – 21.2 mL	Different - See Comment #3 below.
Internal Diameter	0.039" (0.099cm) - 0.103" (0.26 cm)	0.102" (0.26 cm) – 0.133" (0.34 cm)	Different – See Comment #4 below.
External Diameter	0.089" (0.23 cm) - 0.152" (0.39 cm)	0.140" (0.36 cm) – 0.209" (0.53 cm)	
Fluid path Components/Materials			
Spike	Acrylonitrile butadiene styrene	Same	No Differences
IAC Spike Assembly	N/A	High density polyethylene (Vent Housing) Acrylic (w/non-woven nylon substrate) (Air Vent) Ethylene Vinyl Acetate Copolymer (Non-Vented Cap)	Different – See Comment #5 below.
Drip Chamber	Polyvinyl Chloride (PVC)	Same	No Differences
Drop Former	N/A	Teflon (Stainless Steel Coating) Stainless Steel (Cannula)	Different – See comment #6 below.

Table 4. Device Comparison

Technological Characteristics	**Predicate Device** Device Name: K112893	**Proposed Devices** Device Name: K203609	Assessment of Differences
		Low density polyethylene (Cannula Housing) Rubber (synthetic polyisoprene) (Blue Plug)	
Tubing	Polyvinyl chloride (PVC)	Same	No Differences
Clearlink	Polycarbonate (Inlet/Outlet) Silicone (Gland) Polycarbonate (Center Post)	Same	No Differences
Interlink Housing	N/A	Copolyester, Transparent, Clear (Housing) Silicone lubricant, Colorless, Transparent (Lubricant) Natural synthetic polyisoprene rubber, Opaque (Septum)	Different – See comment #7 below.
Y-Junction	N/A	Polyvinyl chloride (PVC)	Different – See comment #8 below.
Check Valve	N/A	Polymethyl methacrylate (acrylic) (PMMA) (Inlet/Outlet) Silicone rubber (SI) (Disk)	Different – See comment #9 below.
Male Luer	Acrylonitrile butadiene styrene	Same	No Differences
Female Luer	Polyester (PES)	Same	No Differences

Discussions of Differences in Technological Characteristics:

*Note: All performance testing / design control activities has been conducted and has confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness. See Discussion of Nonclinical Tests below for standards/methods used to evaluate these technological characteristic differences.

Comment #1 (Indications for Use): Minor rewording of the Indications for Use statement has been made to better align with 21 CFR 880.5440 and for the purpose of streamlining the information provided to the user. This minor modification does not alter the disease or condition the device will diagnose, treat, prevent, cure/mitigate, or the patient population for which the device is intended to be used. In addition, the minor rewording does not reflect a different anatomical site from which a disease state or population may be inferred.

Comment #2 (Length): The predicate device comparatively has a shorter length than some of the proposed devices. The proposed devices offer sets with different lengths, allowing the clinician to select the appropriate one for the administration of the intended therapy. This may include clinicians requiring sets with longer lengths to ensure delivery of solutions without unnecessary manipulations of the set, such as the addition of an extension set to extend the length of the set. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #3 (Priming Volume): Due to longer tubing lengths, the priming volumes of the proposed devices are larger than the predicate device. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #4 (Internal/External Diameter): The proposed devices tubing inner / outer diameters are nominally greater than the predicate device tubing inner / outer diameter. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #5 (IAC Spike Assembly): This material has been used in another Baxter cleared device (cleared in K153158 (12/28/2015) and K150860, (04/16/2015)) with the same/similar intended use and with the same type and duration of contact. Design control activities have been conducted and confirmed that there is no impact to safety or effectiveness for this application. In addition the IAC Air Vent (part of the IAC Spike Assembly) cleared under K153158 and K150860 is changing material from versapor R to versapor RC. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #6 (Drop Former): This material has been used in another Baxter cleared device (cleared in K153158 (12/28/15) and K161323, 11/30/2016)) with the same/similar intended use and with the same type and duration of contact. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #7 (Interlink Housing): This material has been used in another Baxter cleared device (cleared in K123868: INTERLINK System (cleared January 8, 2013) with the same/similar intended use and with the same type and duration of contact. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #8 (Y-Junction): The predicate does not have a Y-Junction. See note above for standards/methods used to evaluate the different technological characteristics.

Comment #9 (Check Valve): This material has been used in another Baxter cleared device (cleared in K153158, 12/28/15) with the same/similar intended use and with the same type and duration of contact. See note above for standards/methods used to evaluate the different technological characteristics.

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 functional performance of the proposed devices:

Luer Tests on male Luer Lock Connector:

- ISO 80369-7 : 2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.

Luer Tests on Female Luer:

- ISO 594-1 : Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2 : Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings

Particulate Matter Testing:

- USP <788> Method 1: Particulate Matter in Injections

Non-DEHP Claim Verification (< 0.1% DEHP):

- Per Baxter Test Method (as tested in K161808)

The remaining bench tests were conducted per Baxter test method:

- Solvent Bond Pressure Test
- Solvent Bond Tensile Strength Test
- Cap Removal
- Spike Insertion/Removal force test
- Drop Volume Accuracy Test
- Water Entry Pressure Test
- Check Valve Opening Pressure
- Check Valve Back Flow Test

- Check Valve High Pressure Test
- Interlink Leak Test
- Interlink Vacuum Test
- Clearlink Y-Site Pressure Test
- Clearlink Y-Site Back Pressure Test
- Clamp 24 Hour Shut-Off Test
- Clamp Pressure Test
- Roller Clamp Flow Rate Accuracy Test
- Hemostat Shut Off Test
- Flow Stability Test
- Pump Compatibility (Continuous bubble test, Accumulated bubble test, Administration Set Integrity After Maximum Delivery, and Flow Rate Accuracy).

Biocompatibility:

In accordance with ISO 10993-1 , the Administration (IV) Sets is classified as: External Communicating, Blood Path Indirect , Prolonged (24 hours to 30 days) . The following testing was conducted:

- Cytotoxicity ISO 10993-5:2009
- Sensitization ISO 10993-10:2010
- Intracutaneous Reactivity ISO 10993-10:2010
- Acute Systemic Toxicity ISO 10993-11:2017
- Material Mediated Pyrogen ISO 10993-11:2017
- Sub-chronic Toxicity ISO 10993-11:2017
- Hemolysis ISO 10993-4:2017

Sterility:

The following testing was conducted post simulated distribution per ASTM D4169 “Standard Practice for Performance Testing of Shipping Containers and Systems”:

- Sterile Barrier Packaging Testing performed on the proposed devices:

- Bubble leak testing - ASTM F2096 “Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)”
- ASTM F1608 - “Standard Test Method for Microbial Ranking of Porous Packaging Materials”
- ISO 5636-5 – “Paper And Board - Determination Of Air Permeance (Medium Range) - Part 5: Gurley Method”

- Sterile Fluid Path Testing performed on the proposed devices:
  - 6 psi Pressure integrity test – per Baxter test method
  - Dye penetration test – ASTM F1929 “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”
  - Standard Test Method for Microbial Ranking of Porous Packaging Materials - ASTM F1608 “Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)”
- Shelf life of 2 years is validated using the FDA recognized standard ASTM F1980 “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”
- Sterilization:
  - Dose establishment – ISO 11137-2 “Sterilization of health care products – Radiation-Part 2: Establishing the sterilization dose.”
  - Process validation – ISO 11137-1 “Sterilization of health care products-Radiation-Part1: Requirements for development, validation and routine control of a sterilization process for medical devices.”
- Pyrogen Test Method
  - Extraction Method - USP<161> “Transfusion and Infusion Assemblies and Similar Medical Devices, in Biological Tests, U.S. Pharmacopeia 43/NF 38.”
  - Limulus Amebocyte Lysate (LAL) Method - USP<85> “Bacterial Endotoxins Test, in Biological Tests, U.S. Pharmacopeia 43/NF 38.”

Microbial Ingress Testing:

Baxter has conducted testing on all potential points of microbial entry into the sterile fluid pathway of the proposed devices subject to this premarket notification. The spike,

injection sites and Luer Connector Sites were tested following Baxter's test method (as tested in K180739). All test results meet their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

CONCLUSION:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The proposed Intravascular Administration Sets are substantially equivalent to the Solution Administration Sets (cleared under K112893) with respect to the indications for use, target populations, treatment method, and technological characteristics.