March 14, 2025

Baxter Healthcare Corporation
Meaghan Bonn
Principal Regulatory Affairs Specialist
25212 W IL Route 120
Round Lake, Illinois 60073

Re: K243529
Trade/Device Name: Solution Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, FMG, FPB
Dated: February 6, 2025
Received: February 12, 2025

Dear Meaghan Bonn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243529

Device Name
Solution 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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K243529 - 510(k) Summary

SUBMITTER:

Name: Baxter Healthcare Corporation
Address: One Baxter Parkway
Deerfield, Illinois 60015
Telephone Number: (224) 948-2000
Date Prepared: March 14, 2025

CONTACT PERSON:

Meaghan Bonn
Principal Specialist, Regulatory Affairs
25212 West Illinois Route 120
Round Lake, IL 60073
Telephone: (224) 270 6470
Fax: (224) 270 4119

IDENTIFICATION OF THE DEVICE:

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

Trade/Device Name: Solution Administration Sets
Common/Usual Name: Stopcock, I.V. Set
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FMG

Trade/Device Name: Solution Administration Sets

Common/Usual Name: Filter, infusion line
Classification Panel: 80 General Hospital

Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPB

PREDICATE DEVICE:

Table 1. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Intravascular Administration Sets	Baxter Healthcare Corporation	K203609	September 30, 2021

SUBJECT DEVICE:

Table 2. Subject Device Set Names per Product Family

Product Family	Product Name
Basic Solution Sets	**Solution Set (X5, with varied lengths)** **Basic Solution Set** **Solution Set with DUO-VENT Spike (X2, with varied lengths)** **INTERLINK System Y-Type Solution Set** **IV Fat Emulsion Administration Set** **Non-DEHP IV Fat Emulsion Administration Set (X2, with varied lengths)** **INTERLINK System Solution Set with DUO-VENT Spike** **INTERLINK System Solution Set (X3, with varied lengths)** **CLEARLINK System Solution Set (X3, with varied lengths)** **CLEARLINK System Non-DEHP Solution Set with DUO-VENT Spike** **CLEARLINK System Non-DEHP Solution Set (X4, with varied lengths)** **Non-DEHP Solution Set with DUO-VENT Spike**

	(X2, with varied lengths)
CONTINU-FLO Sets	**CONTINU-FLO Solution Set (X4, with varied lengths)** **CLEARLINK System CONTINU-FLO Solution Set (X9, with varied lengths)** **CONTINU-FLO Solution Set with DUO-VENT Spike** **Non-DEHP CONTINU-FLO Solution Set** **CLEARLINK System Vented CONTINU-FLO Solution Set** **CLEARLINK System Non-DEHP CONTINU-FLO Solution Set (X11 with varied lengths)** **CLEARLINK System Non-DEHP CONTINU-FLO Solution Set with DUO- VENT Spike (X3, with varied lengths)** **INTERLINK System CONTINU-FLO Solution Set (X2, with varied lengths)** **CLEARLINK System Solution Set with DUO-VENT Spike (X3, with varied lengths)**
Secondary Sets	**CLEARLINK System Secondary Medication Set** **CLEARLINK System Secondary Medication Set with DUO-VENT Spike** **CLEARLINK System Non-DEHP Secondary Medication Set with DUO-VENT Spike (X2, with varied lengths)**
Chemotherapy Sets	**INTERLINK System Vented PE-lined Solution Set with 0.2 Micron Filter** **INTERLINK System PE-lined Solution Set with 0.2 Micron Filter** **CLEARLINK System Vented PE-lined Solution Set with 0.2 Micron Filter** **CLEARLINK System PE-lined Solution Set with 0.2 Micron Filter (X2, with varied lengths)** **CLEARLINK System PE-lined Solution Set with DUO-VENT Spike** **PE lined Solution Set with DUO-VENT Spike** **INTERLINK System PE-lined Solution Set with DUO-VENT Spike**
Stand-Alone Sets	**Large Bore Stopcock** **Two Gang Large Bore Stopcock Manifold** **Three Gang Large Bore Stopcock Manifold** **3-Port Manifold with Check Valves**

Table 3. Proposed Representative Solution Administration Set Configurations

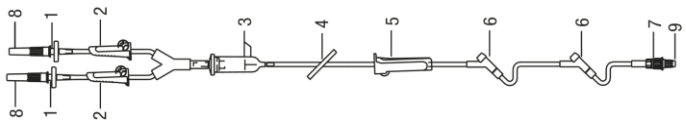
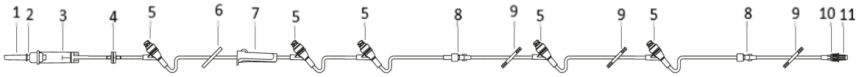
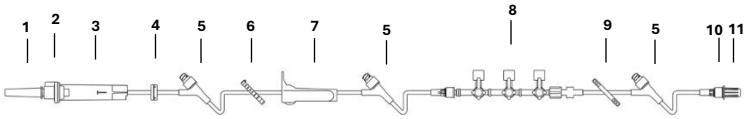
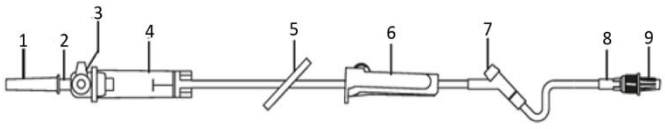
Code #	Device Description	
1C8581	Interlink System Y-Type Solution Set 79” (2.0 m) 	1. Spike Tip Protector 2. Spike 3. Roller Clamp 4. Drip Chamber 5. Slide Clamp 6. Interlink Y-Site 7. Male Luer 8. Male Luer Cap
1C8722	Clearlink System CONTINU-FLO Solution Set 108” (2.7 m) Extension Set 20” (50cm) 3.3 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
2C6256	Clearlink System CONTINU-FLO Solution Set 124" (3.12 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. Stopcock Manifold 9. Slide Clamp 10. Male Luer 11. 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
2C8548	Clearlink System Vented CONTINU-FLO Solution Set 104” (2.6 m)	1. Spike Tip Protector 2. Spike 3. Air Vent

Table 3. Proposed Representative Solution Administration Set Configurations

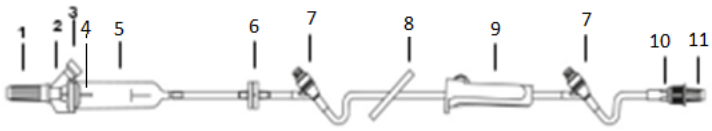
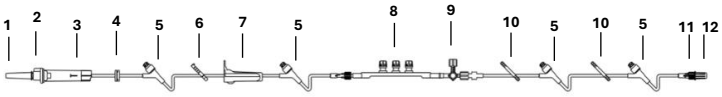
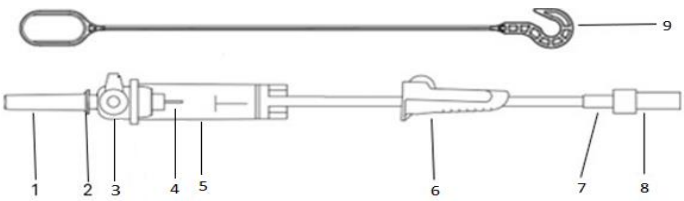
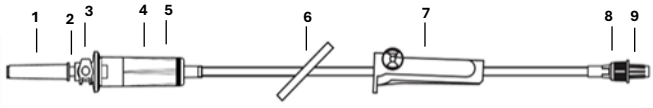
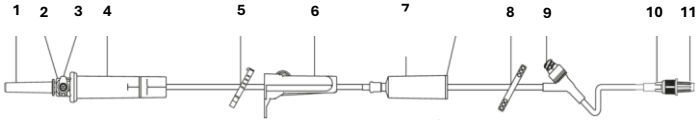
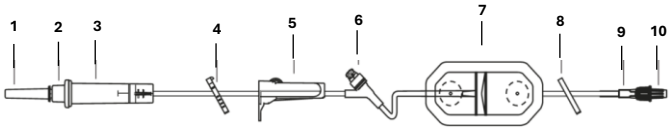
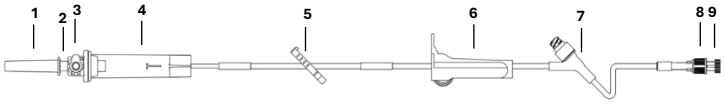
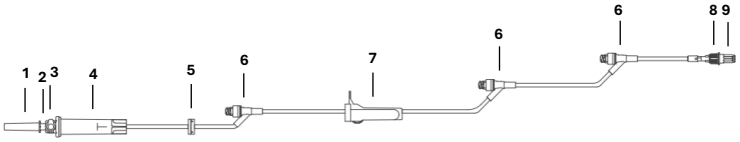
Code #	Device Description	
		4. Drop Former 5. Drip chamber 6. Check Valve 7. Clearlink Y-site 8. Pump Compatible Slide Clamp 9. Roller Clamp 10. Male Luer 11. Male Luer Cap
2C8931	Clearlink System CONTINU-FLO Solution Set 128” (3.21m) 	1. Spike Tip Protector 2. Spike 3. Drip Chamber 4. Check Valve 5. Clearlink Y-Site 6. Pump Compatible Slide Clamp 7. Roller Clamp 8. Manifold 9. Stopcock 10. Slide Clamp 11. Male Luer 12. Male Luer Cap
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. Drop Former 5. Drip Chamber 6. Roller Clamp 7. Male Luer 8. Male Luer Cap 9. Hanger
2H8405	Non – DEHP Solution Set with DUO-VENT Spike 93” (2.4 m) 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Solution Filter 6. Slide Clamp 7. Roller Clamp 8. Male Luer 9. Male Luer Cap
2R8480	Clearlink System Non – DEHP Solution Set with DUO-VENT Spike 103” (2.6m) 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Pump compatible Slide Clamp 6. Roller Clamp 7. IV Express filter 8. Slide Clamp

Table 3. Proposed Representative Solution Administration Set Configurations

Code #	Device Description	
		9. Clearlink Y-Site 10. Male Luer 11. Male Luer Cap
2R8486	Clearlink System Non-DEHP Solution Set 107" (2.7m) 	1. Spike Tip Protector 2. Spike 3. Drip Chamber 4. Pump Compatible Slide Clamp 5. Roller Clamp 6. Clearlink Y-Site 7. Filter 8. Slide Clamp 9. Male Luer 10. Male Luer Cap
2R8875	Clearlink System Solution Set with DUO-VENT Spike 117" (2.9m) 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Pump Compatible Slide Clamp 6. Roller Clamp 7. Clearlink Y-Site 8. Male Luer 9. Male Luer Cap
ALT2403	Clearlink System – QuickStay Set 	1. Spike Tip Protector 2. Spike 3. Air Vent 4. Drip Chamber 5. Check Valve 6. Clearlink Y-Site 7. Roller Clamp 8. Male Luer 9. Male Luer Cap

REASON FOR SUBMISSION:

The basis for this premarket notification is (where applicable):

1. A change to the sterile fluid path distal tip protector (vented to non-vented) and material of construction.
2. A modification to the proximal Luer tip protector design.
3. A modification to the male and female Luers for dimensional compliance to ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*

4. A change in design of the top end spike and chamber and expansion of non-DEHP product portfolio.
5. Updates to product labels, including:
    a. Addition of expiration dating,
    b. Changes in indications for use
    c. Update to the pump compatibility statement and
    d. Implementation of other clarifying information to comply with Baxter's labeling standards.

These modifications do not impact the intended use, fundamental scientific technology of the devices, or impact safety or effectiveness of the devices.

DESCRIPTION OF THE DEVICE:

The proposed devices consist of Solution Administration Sets. These devices include Basic, Secondary, CONTINU-FLO solution sets, Stand-Alone devices and Chemotherapy devices (see Table 2 for a list of subject device set names per product family). They are single use disposable, non-pyrogenic, sterile devices intended for the administration of fluids from a container into the patient's vascular system.

The Basic solution sets consist of a combination of the following components: spike tip protector, non-vented or DUO-VENT macro or micro spike with a non-DEHP or DEHP drip chamber, DEHP or non-DEHP tubing, slide clamp, regulating roller clamp or On/Off roller clamp, Clearlink Luer activated valve (LAV) or Interlink injection site, 0.2 or 1.2 micron inline filter, and two-piece male Luer lock with cap or one-piece male luer and with cap. The Basic solution sets are used to administer solutions directly from a container to a patient vascular system. These sets can be used with or without a Baxter infusion pump.

The Secondary solution sets consist of a combination of the following components: spike tip protector, non-vented or DUO-VENT spike with a DEHP or non-DEHP drip chamber, non-DEHP or DEHP tubing, regulating roller clamp or On/Off roller clamp, two-piece male Luer lock with cap or one-piece male Luer with cap and hanger. Secondary solution sets are used in conjunction with CONTINU-FLO solution sets to administer intermittent fluids to the patient.

The CONTINU-FLO solution sets consist of a combination of the following components: spike tip protector, non-vented, vented or DUO-VENT macro or micro spike with a DEHP or non-DEHP drip chamber, non-DEHP or DEHP tubing, backcheck valve, slide clamp, regulating roller clamp or On/Off roller clamp, Clearlink Luer activated valve (LAV) or Interlink injection site, 3 port manifold, 4-way large bore stopcock, female Luer Lock and two-piece male Luer lock with cap. The CONTINUFLO 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.

The Stand-Alone devices are 4-way large bore stopcocks with non-vented female cap, Luer-Lock nut and a vented male Luer cover and 3 port manifolds with male Luer breather cap and Luer Lock Cap. The Stand-Alone devices are used in combination with IV sets to administer solutions directly from a container to a patient's vascular system.

The Chemotherapy devices consist of a combination of the following components: a spike tip protector, vented spike or non-vented spike, non-DEHP drip chamber, PE lined tubing, slide clamp, 0.2-micron filter, roller clamp, Clearlink Luer activated valve (LAV) or Interlink injection site, two-piece male Luer lock with cap or one-piece male Luer with cap. The Chemotherapy sets are used to administer solutions directly from a container to a patient vascular system. These sets can be used with or without a Baxter infusion pump.

These devices were previously cleared under 510(k) premarket notification K223175 on March 10, 2023, K203609 on September 30, 2021, K180739 on May 28, 2019, K172544 on September 22, 2017, K161808 on June 21, 2017, K153158 on December 28, 2015, K142011 on August 18, 2014, K130245 on March 01, 2013, K123868 on January 8, 2013, K112893 on October 18, 2011 and K952074 on July 27, 1995, K160007 on December 19, 2016, K150860 on April 16, 2015.

INDICATIONS FOR USE:

For the administration of fluids from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are substantially equivalent to the predicate devices K203609, previously cleared under 510(k) premarket notification on September 30, 2021. 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

Features	Predicate Devices Cleared under K203609	Subject Devices, K243529	Assessment of Differences
Intended Use	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Same	N/A
Indication for Use	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Same	N/A
Regulation Number	21 CFR 880.5440	Same	N/A
Product Code	FPA	FPA, FMG, FPB	Addition of stopcocks and manifolds and Infusion Line (In-Line) Filter products.
Sterility	Sterile; Radiation	Same	N/A
Sterility Assurance Level	10^{-6}	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Shelf Life	2 years	Same	N/A
Priming Volume	6.1 mL – 21.2 mL	0.55 mL – 21.2 mL	The subject devices include a wider range of priming volumes. Set sizing is based on clinical uses. The complete set meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
Inner Diameter	0.102" (0.26 cm) - 0.133" (0.34 cm)	Same	N/A
Outer Diameter	0.140" (0.36 cm) - 0.209" (0.53 cm)	Same	N/A
Fluid Path Components/Materials			
DuoVent Spike	60 DPM: ABS, PVDF, HDPE 10 DPM: ABS, SS, PI, PVDF, HDPE	Same	N/A

Table 4. Device Comparison

Features	Predicate Devices Cleared under K203609	Subject Devices, K243529	Assessment of Differences
Non-Vented Spike	10 DPM: ABS 60 DPM: ABS, SS, PI	Same	N/A
Vented Spike	60 DPM: ABS, SS, LDPE, Acrylic	60 DPM: Same 20 DPM: ABS, HDPE, Acrylic	The 20 DPM is sourced from a different supplier. Both devices include industry standard spikes compliant to ISO 8536-4 with geometry and materials compliant to ISO 8536-4 and ISO 10993-1, therefore the difference does not raise any new issues of safety and effectivity.
Drip Chamber	PVC nDEHP PVC	Same	N/A
Tubing	PVC nDEHP PVC	PVC: Same nDEHP PVC: Same PE Lined: DEHP, EVA, LLDPE	The PE lined tubing is used in Baxter cleared devices with the same/similar intended use and with the same type and duration of contact. All tubing types meet the performance requirements of ISO 8536-4 and material safety of ISO 10993-1 therefore the difference does not raise any new issues of safety and effectivity.
Injection Site	Clearlink: PC, Silicone Interlink: COPE, PI, Silicone	Same	N/A
Y-Junction	PVC	Same	N/A
Check Valve	PMMA, Silicone Rubber	Same	N/A

Table 4. Device Comparison

Features	Predicate Devices Cleared under K203609	Subject Devices, K243529	Assessment of Differences
Stopcock	N/A	PSU, HDPE, PVC	This device is cleared within another Baxter submission with the same/similar intended use and same duration of contact. Stopcocks meet the performance requirements of ISO 80369-7 and material safety of ISO 10993-1 therefore the difference does not raise any new issues of safety and effectivity.
3-Port Manifold	N/A	COPE, Silicone Rubber, ABS	This device is cleared within another Baxter submission with the same/similar intended use and same duration of contact. Manifolds meet the performance requirements of ISO 80369-7 and material safety of ISO 10993-1 therefore the difference does not raise any new issues of safety and effectivity.
Male Luer	ABS, LDPE, Acrylic	Same	N/A
Female Luer	PES	Same	N/A
Filter	Inline 0. 2µm: PES, PVDF, Acrylic Inline 1.2µm: Acrylic, PES, PTFE	Inline 0. 2µm: Same Inline 1.2µm: Same In drip chamber: 15µm Nylon, ABS	The 15-micron filter is used in Baxter cleared devices with the same/similar intended use and with the same type and duration of contact. All filter membranes meet the performance requirements of ISO 8536-4 and material safety of ISO 10993-1 therefore the difference does not raise any new issues of safety and effectivity.

DISCUSSION OF NONCLINICAL TESTS:

Bench tests listed were conducted for the Solution Administration Sets and were found to be in conformance with FDA recognized standards ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*. Performance testing includes mechanical (tensile strength) pressure (burst, leakage, backflow, internal), stress cracking, resistance, torque, spike insertion/removal force, drop form accuracy, vacuum, pump / set integrity, DEHP content.

Filter performance testing included particulate retention, integrity, air filter flow. Particulate matter testing was conducted in accordance with USP <788>Particulate Matter in Injections and met the USP Acceptance criteria.

Microbial Ingress testing was conducted on all potential points of microbial entry into the sterile fluid pathway of the proposed devices subject to this premarket notification following Baxter's testing strategy (as previously cleared under K223175 (cleared on March 10, 2023)) of challenging the connections during simulated clinical use to ensure the absence of microbial ingress into the sterile fluid path. All test results meet their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

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BIOCOMPATIBILITY:

In accordance with ISO 10993-1, the Solution Administration Sets are classified as: external communicating device, indirect blood path, prolonged contact duration. The proposed devices are biocompatible and appropriate for its intended use.

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices and FDA-2013-D-0350 Guidance for Industry and FDA Staff, "*Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices – Part 1. Evaluation and testing within a risk management process*," All tests were conducted on final, finished device. The biocompatibility tests that were conducted are:

- Cytotoxicity
- Sensitization

- Intracutaneous (Irritation) Reactivity
- Acute Systemic Toxicity
- 30 Day Systemic Repeat Dose Toxicity Study
- Material Mediated Pyrogen
- Hemolysis

STERILITY, PACKAGING AND SHELF-LIFE:

Sterilization process was established per ISO 11137-1: 2006 *Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*; the devices are sterilized via radiation with a minimum Sterility Assurance Level (SAL) of $10^{-6.}$. The Minimum Sterilizing Dose (MSD) required to provide a 10^{-6} SAL for the bioburden (sub) categories was established and validated as per ISO 11137-2: 2013 *Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*, Method 1. The continued validity of the MSD for these bioburden (sub) categories is confirmed via periodic dose audit studies. In addition, routine periodic pre-sterilization bioburden testing is performed for each (sub) category. Package verification testing was performed on the representative devices is in accordance with ISO 11607-1: 2019 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems* (Simulated Distribution performed per ASTM D4169-22 *Standard Practice for Performance Testing of Shipping Containers and Systems*) and included the following inspections to verify sterile barrier packaging requirements were met: visual (ASTM F1886 *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*), seal strength (ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*), and bubble test (ASTM F2096-11 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test*). The products have a 2-year shelf-life that is confirmed via accelerated aging executed via ASTM F1980-21 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*.

CONCLUSION:

The non-clinical data demonstrates that the subject devices are substantially equivalent and perform comparably to the predicate devices that are legally marketed for the same intended use and no new questions of clinical safety and effectiveness was raised.