March 10, 2023

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

Re: K223175
Trade/Device Name: lntravascular Administration Sets with Stopcock and Manifold
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FMG
Dated: January 31, 2023
Received: February 9, 2023

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 (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,

David Wolloscheck, Ph.D.
Acting 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)*
K223175

Device Name
Intravascular Administration Sets with Stopcock and Manifold

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Baxter

K223175- 510(k) Summary

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Meaghan Bonn
Principal Specialist, Regulatory Affairs
25212 West Illinois Route 120
Round Lake, IL 60073
Telephone: (847) 217 6197
Fax: (224) 270 4119

DATE PREPARED: March 10, 2023

IDENTIFICATION OF THE DEVICE:

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

PREDICATE DEVICE:

Table 1. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Stopcock and I.V. Solution Administration Sets with Stopcocks	Baxter Healthcare Corporation	K130245 (Codes: 2C6607 and 2C6255)	March 1, 2013

REASON FOR SUBMISSION:

The basis for this premarket notification is a change which involves the inclusion of an expiry date on all packaging configuration of the proposed devices and update to the two

piece luer to be dimensionally compliant to ISO80369-7. Additionally, updates are being made to the product labels, including a minor rewording of the indications for use, an update to the pump compatibility statement and implementation of other clarifying information to comply with Baxter's labeling standards. These modifications do not impact the intended use or the fundamental scientific technology of the devices.

DESCRIPTION OF THE DEVICE:

The proposed devices consist of Intravascular Administration 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.

The proposed devices consist of a spike tip protector, non-vented spike, drip chamber, tubing, check valve, slide clamp, regulating roller clamp, Clearlink Luer activated valve (LAV), Interlink injection site, 3 Port Manifold, Stopcock, female Luer, two-piece male Luer lock and male Luer cap. The proposed devices 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.

These sets were previously cleared under 510(k) premarket notification K932512 on Feb 22, 1994. The devices covered in this submission are substantially equivalent to the predicate devices, previously cleared under 510(k) premarket notification K130245 on March 1, 2013. The intended use and function of the proposed devices are equivalent to the predicate devices.

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 K130245 (Codes 2C6607 and 2C6255), previously cleared under 510(k) premarket notification on March 1, 2013. The intended use and function of the proposed devices are equivalent to the predicate devices.

Table 2 is a device comparison table outlining the differences between the predicate and proposed devices.

Table 2. Device Comparison

Features	**Predicate Devices** **Stopcock and I.V. Solution Administration Sets with Stopcocks. K130245** ***(Codes: 2C6607 and 2C6255)***	**Proposed Devices** **Intravascular Administration Set with Manifold and Stopcock** **K223175**	**Assessment of Differences**
Indication for Use	To administer fluids from a container into the patient's vascular system through a vascular access device.	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Similar – See Comment # 1
Regulation Number	21 CFR 880.5440	Same	N/A
Product Code	FMG	Same	N/A
Sterility	Sterile; Gamma Irradiation	Same	N/A
Sterility Assurance Level	10^{-6}	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Length	41" (103 cm) - 123" (316 cm)	40" (101 cm) - 130" (333 cm)	Different- See Comment # 2
Priming Volume	6.2 mL – 19.8 mL	6.2 mL - 21.8 mL	Different – See Comment # 3
Inner Diameter	0.102" (0.26 cm) - 0.111" (0.28cm)	Same	N/A
Outer Diameter	0.133" (0.34 cm) - 0.152" (0.39 cm)	Same	N/A
Fluid path Components/Materials			
Spike & Drip Chamber Assembly	Acrylonitrile butadiene styrene (Spike)	Same (Spike)	N/A
	Polyvinyl Chloride (PVC) (Drip Chamber)	Same (Drip Chamber)	
Tubing	Polyvinyl chloride (PVC)	Same	N/A
Check Valve	Polymethyl methacrylate (acrylic) (PMMA) (Inlet/Outlet)	Same	N/A

	Silicone rubber (SI) (Disk)		
Interlink Injection Site	Copolyester (Housing) Silicone lubricant, (Lubricant) Natural synthetic polyisoprene rubber, (Septum)	Same	N/A
Clearlink	Polycarbonate (Inlet/Outlet) Silicone (Gland) Polycarbonate (Center Post)	Same	N/A
4-way stopcock (Large Bore)	Polysulfone (Housing) Polyethylene (Handle) Polycarbonate (Luer Lock Nut)	Same	N/A
3-Port Manifold	N/A	Polyester (Housing) Silicone rubber (SI) (Disk) Acrylonitrile butadiene styrene (Collar)	Different – See Comment #4
Male Luer	Acrylonitrile butadiene styrene (ABS) (Luer Body)	Same	N/A
Female Luer	Polyester (PES)	Same	N/A

Discussion of difirences in technological characteristics.

Comment# 1- 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: The proposed devices offer sets with different lengths and injection sites, allowing the clinician to select the appropriate one for the administration of the intended therapy. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness.

Comment # 3: The proposed devices offer sets with different lengths and injection sites, allowing the clinician to select the appropriate one for the administration of the intended therapy. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness.

Comment # 4: This material has been used in another Baxter cleared device (cleared in K932512 (22/02/1994)) 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.

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 3) were conducted for the Intravascular Administration Sets with Stopcock and Manifold and were found to be in conformance with the following FDA recognized standards:

Table 3. Performance Data

Test
ISO 80369-7 Luer Tests on male Luer Lock Connector "Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications"
ISO 594-1 "Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements"
ISO 594-2

Test
"Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings"

Biocompatibility:

In accordance with ISO 10993-1, the IV Administration Set with stopcock and manifold is 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

Particulate matter testing was conducted in accordance with USP <788>Particulate Matter in Injections and met the USP Acceptance criteria.

Sterility:

The proposed devices are sterilized with gamma radiation. The products are in the bioburden (sub) category "General Sets Labeled Sterile" or "General Small Devices Labeled Sterile". The Minimum Sterilizing Dose (MSD) required to provide a 10^{-6} Sterility Assurance Level (SAL) for these (sub) categories was established and validated at the manufacturing facility as described in ANSI/AAMI/ISO 11137-2, "Sterilization of health care products – Radiation-Part 2: Establishing the sterilization dose." The dose setting method used includes, but is not limited to, Method 1 or VDmax. Generally, the MSDs are between 14.3 – 22.4 kGy. The continued validity of the MSD for each (sub)

category is confirmed via periodic dose audit studies. In addition, routine periodic pre-sterilization bioburden testing is performed for each (sub) category.

Shelf Life:

Baxter has performed aging testing to support a shelf-life claim of 2 (two) years.

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 testing strategy (as previously cleared under K203609 (cleared on Sept 30, 2021)) 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.

CONCLUSION:

The non-clinical data demonstrate that the subject devices are substantially equivalent and perform comparably to the predicate devices that are legally marketed for the same intended use.