June 10, 2021

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

Re: K210335
Trade/Device Name: Blood Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: BRZ
Dated: May 4, 2021
Received: May 11, 2021

Dear James Vangeisen:

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,

Payal Patel
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)*
K210335

Device Name
Blood Administration Set

Indications for Use *(Describe)*
For the administration of blood, blood components or solutions 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.

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510(k) Summary

K210335

June 10, 2021

OWNER:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

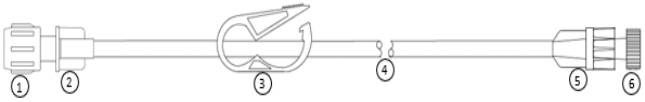
CONTACT PERSON:

James Vangeisen
Principal Specialist, Regulatory Affairs
25212 West Illinois Route 120
Round Lake, IL 60073
Telephone: (224) 270 3308
Fax: (224) 270 4119

IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Blood Administration Set
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: BRZ

Table 1. Proposed Set Configuration

Code #	Device Description	
2N3383	Blood Extension Set, 59” (150 cm), Vol. 4.7 mL 	1. Non-Vented Cap for Female Luer Lock 2. Female Luer Lock 3. Notch Clamp 4. Tube 5. Male Luer Lock 6. Filter Vented Cap for Male Luer Lock

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Blood Administration Sets	Baxter Healthcare Corporation	K993120	November 17, 1999

REASON FOR SUBMISSION:

The basis for this premarket notification is the intent to market an Intravascular (IV) Administration Set (Blood Administration Set). The proposed device in this submission is a single-use, disposable device, intended for the administration of fluids from a container into the patient's vascular system through a vascular access device.

DESCRIPTION OF THE DEVICE:

The proposed device is an IV Administration Set (Blood Administration Set). It is a single use, non-pyrogenic, sterile disposable device intended for the administration of fluids from a container into the patient's vascular system. It can be used to administer solutions, blood, blood products to patients of all ages ranges – neonatal, pediatric, and adult.

The proposed set consists of non-DEHP PVC (< 0.1% DEHP) tubing, a notch clamp, a female Luer lock, a non-vented cap for a female Luer lock, a male Luer lock, and a filter vented cap for a male Luer lock. It can be used to administer solutions, blood, and blood products to the patient. The most common use of this proposed set would be for syringe pump administration as a primary set and as an extension set. This proposed set can also be used as an extension set in combination with gravity and large volume infusion pump blood administration sets (primarily to add length). See Figure 1, Figure 2, and Figure 3 for the clinical use set ups for the proposed device.

Figure 1. Clinical Use Set Up of Proposed Device when used directly with a Syringe as a Primary Syringe Set

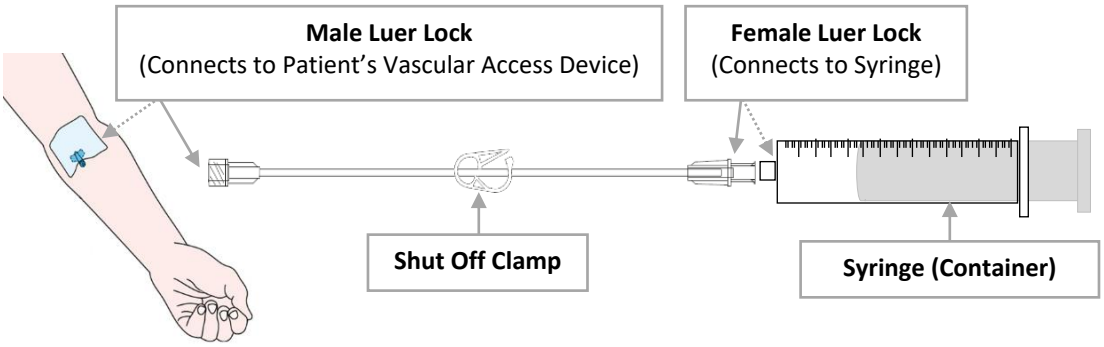


Figure 2. Clinical Use Set Up of Proposed Device when used as an Extension to a Primary Syringe Set

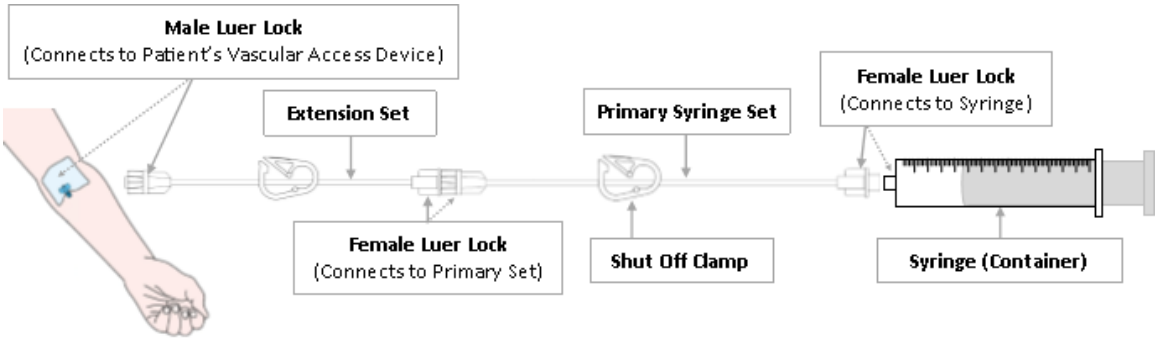
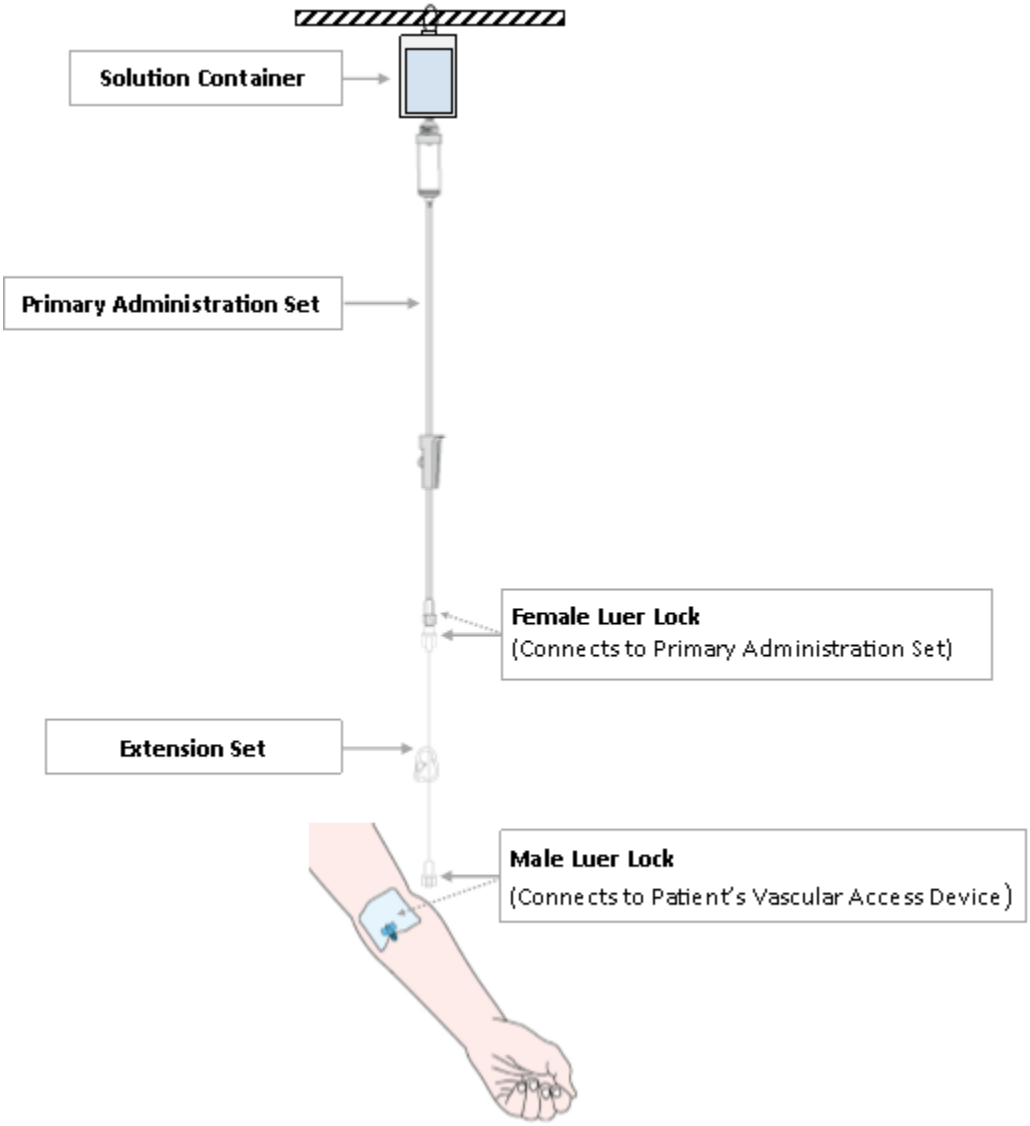


Figure 3. Clinical Use Set Up of Proposed Device when used as an Extension to a Primary Administration Set



INDICATIONS FOR USE:

For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device is substantially equivalent to the predicate device, previously cleared under 510(k) premarket notification K993120 on November 17, 1999. The intended use and function of the proposed device is equivalent to the predicate device.

Table 3 is a device comparison table outlining the differences between the predicate and proposed devices.

Table 3. Device Comparison

Features	Predicate Device K993120	Proposed Device K210335	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 blood, blood components or solutions 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	BRZ	Same	N/A
Sterile	Gamma radiation	Same	N/A
Sterility Assurance Level (SAL)	10^{-6}	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Length	112" (2.8 m) (2C8750)	59" (150 cm) (2N3383)	The predicate device is comparatively longer than the proposed device. Design control activities have been conducted and confirmed, through clinical studies, that the length of the proposed device ensures a safe delivery without excessive manipulation of the set and patient discomfort.

Table 3. Device Comparison

Features	Predicate Device K993120	Proposed Device K210335	Assessment of Differences
			The proposed device can also be used as an extension set that allows the clinician to extend the length of the primary set, when and if needed. A recommended clinical practice, when selecting the overall length of the set, is for the clinician to try and avoid using excessive lengths to minimize residual volumes and retain flow accuracy. From this assessment it can be concluded that the proposed shorter set does not raise different questions of safety and effectiveness when compared to the predicate device.
Fluid Path Components/Materials			
Spike	Acrylonitrile Butadiene Styrene (2C8750)	N/A	The proposed device is an extension set and does not contain a spike.
Blood Chamber	Styrene-Butadiene Blended Copolymer (Chamber and Filter Housing) Polyester -Filter membrane (Mesh) (2C8750)	N/A	The proposed device is an extension set and does not contain a blood chamber.
Tubing	Polyvinyl Chloride (2C8750)	Same	N/A
Injection Site	Clearlink Polycarbonate (Inlet/Outlet Housing) Silicone (Gland) Polycarbonate (Center Post) (2C8750)	N/A	The proposed device is an extension set and does not contain an injection site.
Female Luer Lock	N/A	Polymethyl methacrylate (Acrylic)	The predicate device does not have a female Luer Lock. Design control activities have been conducted and have confirmed that the different

Table 3. Device Comparison

Features	Predicate Device K993120	Proposed Device K210335	Assessment of Differences
			technological characteristics of the proposed devices do not raise different questions of safety and effectiveness.
Male Luer Lock	Acrylonitrile Butadiene Styrene (2C8750)	Same	N/A

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 device is appropriately designed for its intended use.

Performance Data:

The following bench tests (Table 4) were conducted to evaluate the functional performance of the proposed devices:

Table 4. Performance Data

Test	Acceptance Criteria
ISO 80369-7 Luer Tests on male Luer Lock Connector	ISO 80369-7:2016, Clause 6.1.2 or 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5
ISO 80369-7 Luer Tests on female Luer Lock Connector	ISO 80369-7:2016, Clause 6.1.2 or 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5
Tensile Strength Test	ISO 1135-4:2015, Clause 5.3
Leak Test (Pressure Test)	ISO 1135-4:2015, Annex A.2
Notch Clamp Activation Force Test	Activation force ≤50N
Notch Clamp Shut-Off Test	No liquid or air leakage when subjected to 50kPa for 15 sec
Non-DEHP Claim Verification	<0.1% DEHP
Particulate Matter Test	USP <788>
Flow Rate Testing	ISO 1135-4:2015, Section 5.9
ISO 1135-4 Blood Component Compatibility Test	ISO 1135-4, Clause 7.6 and 7.7

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path 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*,'" as recommended in the Intravascular Administration Sets guidance, "*Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]*." Biocompatibility assessments were conducted on a worst case/representative final, finished device for all fluid path materials of the proposed device. The following tests were conducted as part of the biocompatibility assessment for the proposed device:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Acute Systemic Toxicity ISO 10993-11
- 30 Day Systemic Repeat Dose Toxicity Study ISO 10993-11
- Material Mediated Pyrogen ISO 10993-11
- Hemocompatibility ISO 10993-4

Based upon the results, the data supports an ISO 10993-1 categorization of external communicating device, indirect blood path, prolonged contact duration. The proposed device is biocompatible and appropriate for its intended use.

Sterility:

The proposed device is sterilized with gamma radiation. The product is in the bioburden (sub) category "General Sets Labeled Sterile". 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 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 14.2 – 25.0 kGy. The continued validity of the MSD for this (sub) category is confirmed via periodic dose audit studies. Bacterial endotoxins tests were conducted in conformance to USP <85>. The endotoxin limit is 20 EU/device per USP <161>. In addition, routine periodic pre-sterilization bioburden testing is performed for each (sub) category. The sterilization process for the proposed

device was established in accordance with ANSI/AAMI/ISO 11137-1, "*Sterilization of health care products-Radiation-Part 1; Requirements for development, validation and routine control of a sterilization process for medical devices*."

Shelf-Life:

Baxter has performed aging testing to support a shelf-life claim of 3 (three) years.

CONCLUSION:

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