February 28, 2025

Baxter Healthcare Corporation
Bernhard Bartmer
Sr. Regulatory Affairs Specialist
25212 W. IL Route 120
Round Lake, Illinois 60073

Re: K242339
Trade/Device Name: Intravascular Extension Sets and Accessories
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, FPB
Dated: January 29, 2025
Received: January 30, 2025

Dear Bernhard Bartmer:

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, Ph.D.
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)*
K242339

Device Name
Intravascular Extension Sets and Accessories

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:

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"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."

510(k) #:

510(k) Summary

Prepared on: 2025-02-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Baxter Healthcare Corporation
Applicant Address	25212 W. IL Route 120 Illinois Round Lake IL 60073 United States
Applicant Contact Telephone	224-270-2054
Applicant Contact	Mr. Bernhard Bartmer
Applicant Contact Email	bernhard_bartmer@baxter.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Intravascular Extension Sets and Accessories
Common Name	Intravascular administration set
Classification Name	Set, Administration, Intravascular
Regulation Number	880.5440
Product Code(s)	FPA, FPB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192366	Intravascular Extension Sets and Accessories	FPA, FPB

Device Description Summary

21 CFR 807.92(a)(4)

Micro-Volume Extension Set (79'' (200cm))
Mini-Volume Extension Set (59'' (150cm))
Mini-Volume Extension Set (79'' (200cm))
Extension Set, Micro-Volume with 0.2µm filter (79'' (200cm))
Mini-Volume Extension Set (118" (300cm))
Micro-Volume Extension Set (59" (150 cm))
Anti-Siphon Valve
Back Check Valve
Air-Eliminating 1.2 µm Solution Filter
Micro-Volume Extension Set (59" (150 cm)) (with clamp)
Micro-Volume Extension Set with 0.2µm filter (59'' (150cm))
Micro-Volume Catheter Extension Set with 0.2µm filter (10'' (25cm))
Polyethylene (PE) Lined Micro-Volume Extension Set (59'' (150 cm))
Polyethylene (PE) Lined Micro-Volume Extension Set (79'' (200 cm))
Polyethylene (PE) Lined Mini-Volume Extension Set (118'' (300 cm))

The proposed devices are single use disposable devices intended for the administration of fluids from a container to the patient's vascular system. The extension sets consist of a combination of the following components: PVC or PE lined PVC tubing, a clamp, female Luer with non-vented cap, male Luer with filter vented cap. The accessories consist of an anti-siphon valve, back check valve, and 1.2 µm Filter. The accessories are used in combination with IV sets to administer solutions directly from a container to a patient's vascular system.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed devices are substantially equivalent to the to the predicate devices previously cleared under 510(k) Premarket Notification K192366 on July 20, 2020. The proposed devices have the same technical characteristics as the predicate devices. There are no changes in design, material, sterility, or chemical composition as compared to the predicate devices. The only change is the removal of a caution statement on the Direction Insert related to body weight.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following testing was performed in support of the proposed devices:
- Biocompatibility testing

Clinical testing is not applicable for this submission.

The results of biocompatibility testing from these studies support the removal of caution statement on Direction Insert related to body weight, which is the basis for this submission.