June 16, 2023

Fresenius Kabi
℅ Jason Ma
Sr. Manager, Regulatory Affairs
Fresenius Kabi USA,LLC
3 Corporate Dr Suite 300
Lake Zurich, Illinois 60047

Re: K221121
Trade/Device Name: Volumat Polyethylene I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 18, 2023
Received: May 18, 2023

Dear Jason Ma:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221121

Device Name
Volumat Polyethylene I.V. Administration Set

Indications for Use *(Describe)*
I.V. Administration Set for the infusion of parenteral fluids and medications from a container into the patient's vascular system through a vascular access device with Agilia VP MC/Volumat MC Agilia pump or gravity only.

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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510(k) SUMMARY- K221121

1. Date Prepared: June 16, 2023

2. Submitter Information

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3. Device Name and Classification

Device Trade Name: Volumat Polyethylene I.V. Administration Set
Common Name: I.V. Administration Set
Classification Name: Intravascular administration set
Regulation Number 21 CFR 880.5440
Regulatory Class: Class II
Product Code: FPA

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4. Predicate Device

Device Trade Name: Intravascular Administration Sets
Common Name: Intravascular Administration Set
Classification Name: 21 CFR 880.5440
Regulatory Class: Class II
Product Code: FPA
510(k) Number: K203609

5. Device Description

The Volumat Polyethylene I.V. Administration Sets (PE Sets) are available for dedicated use with the Agilia Infusion Pump and the Agilia VP MC Pump, or they can administer parenteral fluids and medications by gravity flow. Both the Agilia Infusion Pump and the Volumat I.V. Administration Sets were cleared under K121613. The Agilia VP MC Pump was cleared under K210073. The PE Sets include a spike, drip chamber, roller clamp, upstream/downstream clamp, backcheck valve, pump segment, needle-free port, rotating male luer lock, and tubing.

Set Number	Description
M46441395	Volumat Polyethylene I.V. Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, rotating male luer
M46441995	Volumat Polyethylene I.V. Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46444495	Volumat Polyethylene I.V. Administration Set with spike, air vent, drip chamber, upstream clamp, backcheck valve, upstream needle-free port, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46445495	Volumat Polyethylene I.V. Administration Set with spike, air vent, drip chamber, upstream clamp, backcheck valve, upstream needle-free port, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer

6. Principle of Operation

The range of sets provides options for intermittent or continuous delivery of parenteral fluids (solutions, colloids, parenteral nutrition) and medications (including but not limited to diluted drugs, chemotherapy) through clinically accepted intravenous (I.V.) routes of administration.

The device may be used for Adults and Pediatrics Patients.

7. Indication for Use/ Intended Use

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Indication for Use:

I.V. Administration Set for the infusion of parenteral fluids and medications from a container into the patient's vascular system through a vascular access device with Agilia VP MC/Volumat MC Agilia pump or gravity only.

Intended Use:

Volumat Polyethylene I.V. Administration Sets are intended for the administration of drugs and solutions.

8. Comparison of the Technological Characteristics with the Predicate Device

The technological characteristics of the subject device are substantially equivalent to those of the predicate device in regard to the following technological characteristics:

- Principle of operation and conditions of use of the subject device are the same as those of the predicate device.
- Materials of the proposed device do not raise new questions of safety and effectiveness, as demonstrated by performance testing and biocompatibility evaluation.
- Physical specifications of the subject device are equivalent to those of the predicate device.

A comparison between the predicate device and the subject device is provided in Table 1 and Table 2 below.

Table 1: Summary of Substantial Equivalence Comparison

Technological Characteristics	Volumat Polyethylene I.V. Administration Sets (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
Indication for Use	IV Administration set for the infusion of parenteral fluids and medications from a container into the patient's vascular system through a vascular access device with Agilia VP MC pumps/Volumat MC Agilia pump or gravity only.	For the administration of fluids from a container into the patients' vascular system through a vascular access device.	Similar. Both I.V. administration sets are used to administer fluids from a container to a patient. However, the Subject Device interoperates with infusion systems that have been cleared in other 510(k) submissions including K121613 and K210073..
Operating Mechanism	The Volumat administration sets deliver the intravenous	The Baxter administration sets can be used to deliver	Similar, both devices can be used with an infusion pump or by gravity flow.

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Technological Characteristics	Volumat Polyethylene I.V. Administration Sets (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
	infusions via an infusion pump through a pumping mechanism ("cassette") or by gravity flow.	solutions for gravity or pump by infusion of I.V. fluids.	The predicate device does not have a pumping mechanism ("cassette"). Difference has been verified through performance testing including flow rate accuracy under various environmental conditions (temperature, pressure, humidity) which demonstrate equivalence.
Sterile	Yes	Yes	Same
Non-Pyrogenic	Yes	Yes	Same
Single Use	Yes	Yes	Same
Length	75-105 inches	69-133.5 inches	Similar. The sets included in the subject device range in length from 75 inches to 105 inches which is within the range of the predicate device. Difference tested according to ISO 8536-4 and flow rate accuracy to demonstrate the subject device performance.
Priming Volume	21-27 ml	6.1 to 21.2 mL	Similar. The Volumat set requires more priming volume than the predicate. Bench testing confirmed that the differences in priming volume do not impact safety or effectiveness.
Internal Tube Diameter	0.122 inches	0.102 to 133 inches	Similar internal and external diameter and approximate range of the predicate device. Difference tested to ISO 8536-8 has demonstrated equivalence.
External Tube Diameter	0.164 inches	0.140-0.209 inches	
Components			
Spike	Yes	Yes	Different. The subject device includes an
Drip chamber	Yes	Yes	

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Technological Characteristics	Volumat Polyethylene I.V. Administration Sets (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
Backcheck Valve	Yes	Yes	additional pumping segment. However, no significant difference between the subject and predicate administration sets that would raise new issues of safety or efficacy. The differences have been verified in various aspects to demonstrate the subject device's safety and performance including: Biocompatibility testing according to ISO 10993 collateral standards, Microbial Ingress Testing, and Particulate Testing; Performance Testing according to ISO 8536-4, ISO 80369-20, ISO 8536-8 and ISO 8436-14.
Pump Segment	Yes	No	
Needle Free Port	Yes	Yes	
Male Luer	Yes	Yes	
Roller Clamp	Yes	Yes	
Connector Luer Lock	Yes	Yes	

Table 2: Summary of Material Comparison

Component	Modified Volumat I.V. Administration Set (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
Spike	Polystyrene	Acrylonitrile Butadiene Styrene	Similar, testing to biocompatibility and performance standards demonstrated equivalence
Drip chamber	Polystyrene, styrene-butadiene-copolymer, Polyamide	Polyvinyl Chloride	Different, testing to biocompatibility and performance standards demonstrated equivalence
Backcheck Valve	Methylmethacrylate-Acrylonitrile-Butadiene-Styrene)	Polymethyl methacrylate (acrylic) Silicone Rubber	Similar, testing to biocompatibility and performance standards demonstrated equivalence
Pump Segment	Methylmethacrylate-Acrylonitrile-Butadiene-Styrene	N/A – predicate device does not have a pump segment	Testing to biocompatibility and performance standards demonstrated equivalence

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Component	Modified Volumat I.V. Administration Set (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
Needle Free Port	Methylmethacrylate-Acrylonitrile-Butadiene-Styrene, Copolyester	Polyester	Similar, Testing to biocompatibility and performance standards demonstrated equivalence
Rotating Male Luer Lock	Polyvinylchloride, Acrylonitrile butadiene styrene	Acrylonitrile butadiene styrene	Similar, Testing to biocompatibility and performance standards demonstrated equivalence
Tubing	Polyvinyl chloride, ethylene-vinyl acetate, polyethylene	Polyvinyl chloride	Similar, Testing to biocompatibility and performance standards demonstrated equivalence

9. Substantial Equivalence

Intended Use/Indication for Use—Discussion of Differences

Both the subject and predicate device have the same intended use and similar indication for use. Both I.V. administration sets are used to administer fluids.

Technological Characteristics—Discussion of Differences

- Both the subject and predicate device can be used with an infusion pump or by gravity flow. The subject device delivers the intravenous infusions via an infusion pump through a pumping mechanism (“cassette”) or by gravity flow, and the predicate device does not have a pumping mechanism (“cassette”).

- The subject device ranges in length from 75 inches to 105 inches, which is within the length range of the predicate device.

- The subject device carries more priming volume than the predicate. Bench testing confirmed that the differences in priming volume do not impact safety or effectiveness.

- The subject device includes an additional pumping segment. However, no significant difference between the subject and predicate administration sets that would raise new issues of safety or efficacy.

Conclusion on Substantial Equivalence

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The Volumat Polyethylene I.V. Administration Set has the same intended use and equivalent indication for use as the predicate device. The subject device has similar technological characteristics to the predicate, and the descriptive and performance information provided within this premarket notification demonstrates that:

- any differences do not raise different questions of safety and effectiveness compared to the predicate device; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.

Based on the comparison of the intended use and the technological characteristics, the subject device is substantially equivalent to the currently marketed predicate device.

10.Performance Testing

Performance Testing—Bench

Functional performance bench testing was conducted to demonstrate that the Volumat Polyethylene I.V. Administration Set performs as intended.

The following performance testing was conducted to support the substantial equivalence determination:

- ISO 8536-8
  - Leakage
  - Tensile Strength
  - Storage Tube Volume

- ISO 80369-20
  - Luer Fittings
  - Stress Cracking
  - Resistance to Separation from Axial Loading
  - Resistance to Separation from Unscrewing
  - Resistance to Overriding

- ISO 8536-4
  - Closure-piercing Device Testing
  - Air-inlet Device Testing
  - Tubing Testing
  - Flow Requirements of the Infusion Pump
  - Drip Chamber Testing
  - Clamp Opening and Closing
  - Protective Cap Testing
  - Chemical Compatibility Testing

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- ISO 8536-14
    - Clamps and Flow Regulators Testing

- ISO 11607-1 & 2 and ASTM D4169
    - Sterile Barrier and Packaging Systems and Simulated Shipping

- Particulate USP<788> Particulate Matter in Injections
    - Particulate Testing

- Pump Segment Compatibility Testing with Infusion Pump
- Operation under Temperature, Pressure and Humidity
- Microbial Ingress Testing
- Usability Testing

11.Biocompatibility Testing

Following the FDA Guidance: "Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process", the tests selected were for prolonged, blood path indirect, externally communicating devices. The following biocompatibility tests were successfully conducted on the Volumat Polyethylene I.V. Administration Set:

- Acute Systemic Toxicity
- Hemolysis
- Irritation
- Sensitization
- Cytotoxicity
- Pyrogens
- Subacute/subchronic toxicity

12. Sterilization Validation

Sterilization was achieved by ethylene oxide and meets the requirements of DIN EN ISO 11135:2020, which is equivalent to ISO 11135 (2014-7) + AMD 1 (2018-10). The ethylene oxide sterilization method achieves a Sterilization Assurance Level (SAL) of 10^{-6}.

13. Clinical Testing

No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

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14. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject device, Volumat Polyethylene I.V. Administration Set is substantially equivalent to the predicate device, I.V. Administration Set, cleared under K203609.