



June 2, 2023

Fresenius Kabi  
% Keith Dunn  
Director Regulatory Affairs  
Fresenius Kabi LLC, USA  
3 Corporate Dr Suite 300  
Lake Zurich, Illinois 60047

Re: K220301

Trade/Device Name: Volumat™ Line  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: Class II  
Product Code: FPA  
Dated: May 3, 2023  
Received: May 3, 2023

Dear Keith Dunn:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Forache Bennett". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

For Dr. 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

## Indications for Use

510(k) Number (if known)

K220301

Device Name

Volumat™ Line

Indications for Use (Describe)

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/Volumat MC Agilia pump or gravity only.

Transfusion Set for the infusion of blood and blood derivatives 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- K220301

**1. Date Prepared:** June 2, 2023

### 2. Submitter Information

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### 3. Device Name and Classification

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

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

Set Number	Description
M46441960	Volumat Line IV Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, downstream clamp, needle-free port, and rotating male luer
M46441985	Volumat Line IV Administration Set with non-siliconized spike, air vent, drip chamber, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46442460	Volumat Line IV Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, 1.2micron filter (neutrally charged), downstream clamp, downstream needle-free port, rotating male luer
M46443160	Volumat Line Transfusion Set with spike, roller clamp, drip chamber with 200micron filter, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46443450	Volumat Line IV Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46444160	Volumat Line IV Administration Set with spike, air vent, drip chamber, roller clamp, pump segment, 0.2micron filter downstream clamp, downstream needle-free port, rotating male luer
M46444175	Volumat Line IV Administration Set with non-siliconized spike, air vent, drip chamber, roller clamp, pump segment, 0.2micron filter, downstream clamp, downstream needle-free port, rotating male luer,
M46445260	Volumat Line IV Administration Set with spike, air vent spike, upstream clamp, (5) air vent burette, 150 mL burette with 15µm filter and upstream needle-free port, drip chamber, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46445270	Volumat Line IV Administration Set with spike, air vent spike, upstream clamp, air vent

Set Number	Description
	burette, 150 mL burette with 15µm filter and upstream needle-free port, drip chamber, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46445475	Volumat Line IV Administration Set with non-siliconized 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
M46445660	Volumat Line IV 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
M46445670	Volumat Line IV Administration Set with spike, air vent, drip chamber, upstream clamp, backcheck valve, 2 upstream needle-free ports, roller clamp, pump segment, downstream clamp, downstream needle-free port, rotating male luer
M46445690	Volumat Line IV Administration Sets with spike, air vent, drip chamber, upstream clamp, backcheck valve, upstream needle-free ports, roller clamp, pump segment, downstream clamp, 2 downstream needle-free ports, rotating male luer
M46445780	Volumat Line IV Administration Set with spike, air vent, drip chamber, upstream clamp, backcheck valve, upstream needle-free port, roller clamp, pump segment, downstream clamp, 2 downstream needle-free ports, rotating male luer
M46445860	Volumat Line IV Administration Set with spike, air vent, drip chamber, upstream clamp, backcheck valve, upstream needle-free port, roller clamp, pump segment, 0.2micron filter, 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 and transfusions of blood and blood derivative products.

The device may be used for adult patients. The devices M46445260 and M46445270 may be used for pediatric patients.

## 7. Indication for Use/ Intended Use

### 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.

Transfusion set for the infusion of blood and blood derivatives 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:**

The Volumat™ Line is intended for the administration of drugs, solutions and blood products.

**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. Both devices have a needle free access port. The subject device incorporates a neutral displacement needleless access port with the same intended use

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

**Table 1: Summary of Substantial Equivalence Comparison—Primary Sets**

Technological Characteristics	Volumat™ Line (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
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.  Transfusion set for the infusion of blood and blood derivatives from a container into the patient’s vascular system through a	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.

<b>Technological Characteristics</b>	<b>Volumat™ Line (Subject Device)</b>	<b>Baxter Administration Set K203609 (Predicate Device)</b>	<b>Assessment of Differences</b>
	vascular access device with Agilia VP MC/Volumat MC Agilia pump or gravity only.		
Operating Mechanism	The Volumat administration sets deliver the intravenous infusions via an infusion pump through a pumping mechanism (“cassette”) or by gravity flow.	The Baxter administration sets can be used to deliver solutions for gravity or pump by infusion of I.V. fluids.	Similar, both devices can be used with an infusion pump or by gravity flow. 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	75-115 inches	69-133.5 inches	Similar. The sets included in the subject device range in length from 75 inches to 115 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	20-29 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.  Difference tested to ISO 8536-4 to demonstrate equivalence.
Internal Tube Diameter	0.098 to 118 inches	0.102 to 133 inches	



Technological Characteristics	Volumat™ Line (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
External Tube Diameter	1.61 inches	1.42 to 2.09 inches	Similar internal and external diameter and approximate range of the predicate device.  Difference tested to ISO 8536-8 has demonstrated equivalence.
<b>Components</b>			
Spike	Yes	Yes	Different. The subject device includes an additional pumping segment, downstream filter, and burette, 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.
Drip chamber	Yes	Yes	
Backcheck Valve	Yes	Yes	
Pump Segment	Yes	No	
Downstream Filter	Yes	No	
Needle Free Port	Yes	Yes	
Male Luer	Yes	Yes	
Roller Clamp	Yes	Yes	
Connector Luer Lock	Yes	Yes	
Burette	Yes	No	

**Table 2: Summary of Substantial Equivalence Comparison—Transfusion Sets**

Technological Characteristics	Modified Volumat I.V. Administration Set (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
Indication for Use	Transfusion set for infusion pumps (Agilia VP MC pumps/Volumat	For the administration of fluids from a	Similar. Slight difference but both the subject device

<b>Technological Characteristics</b>	<b>Modified Volumat I.V. Administration Set (Subject Device)</b>	<b>Baxter Administration Set K203609 (Predicate Device)</b>	<b>Assessment of Differences</b>
	MC Agilia pump or gravity only.)	container into the patients' vascular system through a vascular access device.	and predicate device include a blood transfusion set.  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 transfusion via an infusion pump through a pumping mechanism ("cassette") or by gravity flow.	The Baxter administration sets can be used to deliver solutions for gravity or pump by infusion of I.V. fluids.	Similar, both devices can be used with an infusion pump or by gravity flow. 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	110 inches	79 inches	Similar. The transfusion set included in the subject device is longer than the predicate device. Testing did not raise any new issues of safety or efficacy.  Difference tested according to ISO 8536-4 and flow rate accuracy to demonstrate the subject device performance.
Priming Volume	33 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 does not impact safety or effectiveness.

Technological Characteristics	Modified Volumat I.V. Administration Set (Subject Device)	Baxter Administration Set K203609 (Predicate Device)	Assessment of Differences
			Difference tested to ISO 8536-4 to demonstrate equivalence.
Internal Tube Diameter	0.118 inches	0.102 to 133 inches	Similar internal diameter and approximate range of the predicate device.
External Tube Diameter	1.61 inches	1.42 to 2.09 inches	
			Difference tested to ISO 8536-8 has demonstrated equivalence.
<b>Components</b>			
Spike	Yes	Yes	Different. The subject device includes a pump segment, however, no significant difference between the 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.
Drip chamber	Yes	Yes	
Pump Segment	Yes	No	
Needle Free Port	Yes	Yes	
Male Luer	Yes	Yes	
Y-Connector	Yes	Yes	

**Table 3: Administration/Transfusion Set Material Comparison Table**

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

<b>Component</b>	<b>Modified Volumat I.V. Administration Set (Subject Device)</b>	<b>Baxter Administration Set K203609 (Predicate Device)</b>	<b>Assessment of Differences</b>
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
Downstream Filter	Polyacryl, polyethersulfone	N/A – predicate device does not have a downstream filter	Testing to biocompatibility and performance standards demonstrated equivalence
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
Y-Connector	Methylmethacrylate-Acrylonitrile-Butadiene-Styrene	Polyvinyl chloride	Different, testing to biocompatibility and performance standards demonstrated equivalence
Tubing	Polyvinyl chloride, Polyurethane, Polypropylene	Polyvinyl chloride	Similar, Testing to biocompatibility and performance standards demonstrated equivalence
Burette	Acrylonitrile-Butadiene-Styrene, Polyvinylchloride, Copolyester, Polyethylene, Versapor, Stainless steel, Polyamid, Polycarbonate	N/A – predicate device does not have a burette	Different, testing to biocompatibility and performance standards demonstrated equivalence

## 9. Substantial Equivalence Discussion

### 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 with infusion pumps as well as for gravity flow.

### **Technological Characteristics—Discussion of Differences**

Note: All performance testing / design control activities has been conducted and has confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness. See performance testing below for standards/methods used to evaluate these technological characteristic 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”). However, both devices have a pump set interface that was verified through flow rate testing.
- The subject device ranges in length from 75 inches to 115 inches, which is within the length range of the predicate device. Difference tested according to ISO 8536-4 and flow rate accuracy to demonstrate the subject device performance.
- 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. Difference tested to ISO 8536-4 to demonstrate equivalence.
- The subject device includes an additional downstream filter and burette. However, no significant difference between the subject and predicate administration sets that would raise new questions of safety and 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.

### **Conclusion on Substantial Equivalence**

The subject device has the same intended use and equivalent indications as the predicate device. It also has similar technological characteristics to the predicate, and the descriptive as well as the 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 predicate device.

## **10. Performance Testing**

### **Performance Testing—Bench**

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

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

- ISO 8536-8
  - Leakage Testing
  - Tensile Strength Testing
  - Storage Tube Volume Testing
- ISO 80369-20
  - Luer Fittings Leakage Testing
  - 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
  - Fluid Filter Testing
  - Flow Rate Testing of the Infusion Pump
  - Drip Chamber Testing
  - Clamp Opening and Closing
  - Protective Cap Testing
  - Chemical Compatibility Testing
- ISO 8536-14
  - Clamps and flow regulators Testing
- ISO 11607-1 and ASTM D4169
  - Sterile barrier and packaging systems and simulated shipping

- USP<788> Particulate Matter in Injections
  - Particulate Testing
- Pump Segment Compatibility Testing with Infusion Pump
- Operation under Temperature, Pressure and Humidity
- Microbial Ingress 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 I.V. Administration Set:

- Acute Systemic Toxicity
- Hemolysis
- Intracutaneous Reactivity
- Sensitization
- Cytotoxicity
- Pyrogens
- Subacute/subchronic toxicity
- Targeted Chemical Analysis for DEHP

## **12. Sterilization Validation**

Sterilization was achieved by ethylene oxide and meets the requirements of 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.

## **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™



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Line is substantially equivalent to the predicate device, I.V. Administration Set, cleared under K203609.