July 24, 2025

B. Braun Medical Inc
Rushtin Chaklader
Sr. Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K243392
Trade/Device Name: Infusomat® Space Volumetric Infusion Pump Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: June 20, 2025
Received: June 20, 2025

Dear Rushtin Chaklader:

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,

David Wolloscheck -S

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)*
K243392

Device Name
Infusomat® Space Volumetric Infusion Pump Administration Sets

Indications for Use *(Describe)*
The Infusomat® Space Volumetric Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat Space Volumetric Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

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.

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K243392 510(k) SUMMARY

This summary of 510(k) information is being provided in accordance with 21 CFR 807.92.

Submitter Information	
Name	B. Braun Medical Inc.
Address	824 12th Avenue, Bethlehem, PA 18018
Telephone number	(610) 266-0500
Primary contact Title e-mail Telephone number	Rushtin Chaklader Sr. Regulatory Specialist, Regulatory Affairs rushtin.chaklader@bbraunusa.com (610) 984-9312
Secondary contact Title e-mail Telephone number	Tracy Maddock Manager II, Regulatory Affairs tracy.maddock@bbraunusa.com (484) 280-8533
Date prepared	July 24, 2025
Device	
Device Name / Proprietary Name	Infusomat® Space Volumetric Infusion Pump Administration Sets
Common or Usual Name	IV Administration Set
Regulation Name	Intravascular administration set
Regulation Number	21 CFR 880.5440
Device Class	Class II
Product Code(s)	FPA: Set, Administration, Intravascular
Review Panel	General Hospital
Legally marketed device to which equivalence is claimed (predicate)	
Device Name / 510(k)	Infusomat Space Volumetric Infusion Pump Administration Sets / K142036

Device Description

The Infusomat® Space Volumetric Infusion Pump administration sets are sterile, nonpyrogenic, single-use devices for use with the B. Braun Infusomat® Space Volumetric Infusion Pump for pump and gravity administration of fluids.

Each administration set contains a segment of silicone tubing intended to interface with the linear peristaltic mechanism of the pump. There are two connectors at each end of the pump tube segment and a line loading guide to assist the user in loading the pump segment into the pump. Each set also contains a free flow protection clamp. The clamp is specifically designed to interface with a mating receptacle in the pump and is intended to prevent free flow of fluid when the pump door is opened and the set is removed. There are multiple set configurations including basic sets, burette sets, additive sets, filtered sets, epidural sets, low adsorption sets, add-on sets, and blood sets.

This 510(k) is making limited modifications to the predicate device. The subject changes of this 510(k) were related to updates to the tubing length, diameter, and material, as well as component updates to accommodate the changes to the tubing.

Intended Use and Indications for Use

Intended Use

The Infusomat® Space Volumetric Infusion Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Indications for Use

The Infusomat® Space Volumetric Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Substantial Equivalence Discussion

Indications for Use Comparison

The table below includes a comparison of the indications for use between the subject device and that of the predicate device:

Characteristic	**Subject Device** Infusomat Space Volumetric Infusion Pump Administration Sets	**Predicate Device** Infusomat Space Volumetric Infusion Pump Administration Sets, K142036
Indications for Use	The Infusomat® Space Volumetric Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically	The Infusomat® Space Volumetric Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted

Characteristic	**Subject Device** Infusomat Space Volumetric Infusion Pump Administration Sets	**Predicate Device** Infusomat Space Volumetric Infusion Pump Administration Sets, K142036
	accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.	routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.
Prescription Only or Over the Counter	Rx only	Rx only
Intended population	Adults, pediatrics, neonates	Adults, pediatrics, neonates
Environment of Use	Healthcare facilities, home care, outpatient, and medical transport environments	Healthcare facilities, home care, outpatient, and medical transport environments

Discussions of differences in Indications for Use statement

The Indications for Use statement for the subject device is identical to the predicate device.

Discussions of differences in Prescription vs OTC

Both the subject device and the predicate device are prescription devices.

Discussions of differences in intended population

The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use

The environment of use for the subject device is identical to the predicate device.

Technological Characteristics

The proposed administration sets have the same intended use, indications for use, and principles of operation, and the same or similar technological characteristics as the predicate device. Both

the proposed and predicate device are provided sterile for single use. The proposed sets are constructed of similar materials and are manufactured and sterilized utilizing the same processes.

The table below includes a comparison of the technological characteristics between the subject device and that of the predicate device:

	Subject Device **Infusomat Space Volumetric Infusion Pump Administration Sets**	**Predicate Device** **Infusomat Space Volumetric Infusion Pump Administration Sets (K142036)**
Design/Components	The Infusomat® Space Volumetric Infusion Pump administration sets contain a dedicated pump tubing segment and free flow protection clamp that interface with the pump. The free flow protection clamp is intended to prevent free flow of fluid when the pump door is opened and the set is removed. The administration sets are also composed of various combinations of administration set components.	The Infusomat® Space Volumetric Infusion Pump administration sets contain a dedicated pump tubing segment and free flow protection clamp that interface with the pump. The free flow protection clamp is intended to prevent free flow of fluid when the pump door is opened and the set is removed. The administration sets are also composed of various combinations of administration set components.
Set Specifications	**Primary Set length range:** 88 in to 136 in **Set tubing Inner Diameter (ID) and Outer Diameter (OD) range:** IDs from 0.060 in ± 0.002 to 0.187 in ± 0.005 ODs from 0.151 in. ± 0.003 to 0.249 in **Drops/mL:** 10 to 60 **Space Pump Segment Assembly Tubing** Nominal Length: 7.125 inches Outer Diameter: 0.152 in or 0.1614 in (set dependent) Inner Diameter: 0.108 in or 0.118 in (set dependent) **Standard Set Tubing** Nominal Diameter: 0.108 in x 0.152 in or 0.118 in x 0.1614 in (set dependent) Material: 70 durometer clear PVC or 74 durometer clear PVC (set dependent)	**Primary Set length range:** 88 in to 136 in **Set tubing ID and OD range:** IDs from 0.060 in ± 0.002 to 0.187 in ± 0.005 ODs from 0.150 in. ± 0.003 to 0.249 in **Drops/mL:** 10 to 60 **Space Pump Segment Assembly Tubing** Nominal Length: 6.6 in Outer Diameter: 0.152 in Inner Diameter: 0.108 in **Standard Set Tubing** Nominal Diameter: 0.108 in x 0.152 in Material: 70 durometer clear PVC
Material Composition	The material composition of the components of the Infusomat® Space Volumetric Infusion Pump administration sets are commonly used materials for medical devices such as silicone, ABS, LDPE, HDPE, acrylic, PVC, polycarbonate, etc. The materials have been subjected to biocompatibility testing or are present in current legally marketed	The material composition of the components of the Infusomat® Space Volumetric Infusion Pump administration sets are commonly used materials for medical devices such as silicone, ABS, LDPE, HDPE, acrylic, polystyrene, PVC, polycarbonate, etc. The materials have been subjected to biocompatibility testing or are present in current legally marketed

	Subject Device **Infusomat Space Volumetric Infusion Pump Administration Sets**	**Predicate Device** **Infusomat Space Volumetric Infusion Pump Administration Sets (K142036)**
	B. Braun devices under similar conditions of use.	B. Braun devices under similar conditions of use.
Manufacturing and Sterilization Process	The components of the Infusomat® Space Volumetric Infusion Pump Administration Sets are either purchased or manufactured using standard B. Braun injection molding, extrusion and assembly processes. The assemblies and components are solvent bonded to form the finished administration sets. The sets are then packaged, labeled, EtO sterilized and released for sale.	The components of the Infusomat® Space Volumetric Infusion Pump Administration Sets are either purchased or manufactured using standard B. Braun injection molding, extrusion and assembly processes. The assemblies and components are solvent bonded to form the finished administration sets. The sets are then packaged, labeled, EtO sterilized and released for sale.
Priming Volume Range (approximately)	11 to 41 mL	11 to 41 mL
Different configurations of the sets are available, depending upon the required use	Yes	Yes
Set Components	• Universal Chamber Assembly (Spike + Drip Chamber) • Slit Septum Y-Injection Site • SafeLine Y-Injection Site • Normally Closed Back check Valve (Anti Siphon Valve) • Low Pressure Back check Valve • ULTRASITE Y-Site Assembly • Flow restrictor • CARESITE Y-Site Valve Assembly • CARESITE SafeDAY Y-Site Valve Assembly • Male Luer Lock Adapter with vented cap (Spin-lock Connector) • Blood Spike Assembly • Blood Filter Assembly • Female Luer Lock Assembly • Burette Assembly • Nitro Set • Space Pump Segment Assembly • Air Eliminating Filters • Tubing • Clamps	• Universal Chamber Assembly (Spike + Drip Chamber) • Slit Septum Y-Injection Site • SafeLine Y-Injection Site • Normally Closed Back check Valve (Anti Siphon Valve) • Low Pressure Back check Valve • ULTRASITE Y-Site Assembly • Flow restrictor • CARESITE Y-Site Valve Assembly • SafeDAY Valves • Male Luer Lock Adapter with vented cap (Spin-lock Connector) • Blood Spike Assembly • Blood Filter Assembly • Female Luer Lock Assembly • Burette Assembly • Nitro Set • Space Pump Segment Assembly • Air Eliminating Filters • Tubing • Clamps
Biocompatible materials	Yes	Yes

The differences between the subject device and predicate device do not raise any different questions of safety or effectiveness. The subject and predicate devices utilize very similar or identical technological characteristics. There are some differences in materials, specifications, and set components used, however the differences do not raise any different questions of safety or effectiveness. The materials of the subject and predicate devices are similar though not identical; both the subject and predicate devices utilize biocompatible materials that have been qualified for biocompatibility. The set tubing specification range of the subject device is within the overall range of the predicate device. The set components between the subject and predicate devices are also similar, utilizing either the same or comparable components. Any differences in technological characteristics have been adequately qualified to meet the intended use of the device. There are no questions raised by the technological characteristics of the new device that was not applicable to the predicate device and that poses a significant safety or effectiveness concern for the new device.

Summary of Non-Clinical Testing

The proposed Infusomat® Space Volumetric Infusion Pump Administration Sets were subjected to functional and performance testing to demonstrate that the sets perform as intended and to demonstrate substantial equivalence to the predicate device. Only performance testing needed to evaluate the changes compared to the predicate was performed. The following testing was performed:

Biocompatibility	Biocompatibility evaluation in accordance with ISO 10993-1: 2018 "Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process". Tests included cytotoxicity, sensitization, intracutaneous, systemic toxicity, subacute toxicity, material mediated pyrogen, and hemolysis.
Device Performance	Performance testing in accordance with ISO 8536-4 "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed", ISO 8536-8 "Infusion Equipment for Medical Use - Part 8: Infusion Sets for Single Use with Pressure Infusion Apparatus", ISO 8536-14 "Infusion equipment for medical use Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact", and USP 788 "Particulate Matter in Injections". The following tests were performed: visual, occlusion, positive air pressure, positive water pressure, negative pressure, static tensile, dynamic tensile, air tightness, fluid tightness, cyclic opening and closing, 7 day closure, clamp retention, air shut off, fluid shut off, flow consistency, wheel retention, particulate, and chemical testing.
Associate Device (Pump) Testing	Testing included sensor tubing dimensions, PVC content, upstream sensor, downstream sensor, and air-in-line sensor testing

Clinical Tests

No clinical testing was performed as the Infusomat Space Volumetric Infusion Pump Administration Sets do not require clinical studies to demonstrate substantial equivalence with the predicate device.

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Infusomat Space Volumetric Infusion Pump Administration Sets are substantially equivalent to the Infusomat Space Volumetric Infusion Pump Administration Sets cleared under K142036 with respect to the indications for use, target populations, and technological characteristics.