B. Braun Melsugen AG
℅ Andre Kindsvater
Senior Consultant RA & QA
Emergo Global Consulting , LLC
2500 Bee Cave Road
Austin, Texas 78746

Re: K191910
Trade/Device Name: SpaceStation MRI
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ, FRN
Dated: January 29, 2020
Received: February 4, 2020

Dear Andre Kindsvater:

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 Nikhil Thakur
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191910

Device Name
SpaceStation MRI

Indications for Use *(Describe)*
The SpaceStation MRI is a MRI (Magnetic Resonance Imaging) System Rack for the operation of Space Infusion Pumps during MRI examinations (MRI procedures) of adult, pediatric or neonatal patients.

The product is intended to be used by qualified healthcare professionals.

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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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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191910

Device Name
Perfusor® Space Infusion Syringe Pump

Indications for Use *(Describe)*
The Perfusor® Space Infusion Syringe Pump System includes an external transportable electronic infusion syringe pump and pump accessories. The system is 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 system is 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 Perfusor® Space Infusion Syringe Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments (only road ambulances).

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191910

Device Name
Infusomat® Space Volumetric Infusion Pump

Indications for Use *(Describe)*
The Infusomat® Space Volumetric Infusion Pump System includes an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories. The system is 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, irrigation/ablation, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to colloids and cristalloids, blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments. (only road ambulances).

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)

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510(k) Summary - K191910

Administrative Information

01) 510(k) Sponsor

B. Braun Melsungen AG
Carl-Braun-Strasse 1
Melsungen
34212
Germany
Phone: +49 5661 71-1461

02) Contact Person

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Cell Phone: +41 78 843 7077
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: André Kindsvater, Senior Consultant, RA/QA
Email: LST.AUS.ProjectManagement@ul.com.

03) Date Prepared

February 28, 2020

Proposed Device(s)

This is a bundled 510(k), where the summary is organized in 3 sub-sections which correspond to each device bundled within the subject 510(k):

- **Section A)** MRI conditional labeling changes to K062699 Perfusor Space Infusion Syringe Pump (See pages 2 - 4)
- **Section B)** MRI conditional labeling changes to K062700 Infusomat Space Volumetric Infusion Pump (See pages 5 - 7)
- **Section C)** Traditional 510(k) SpaceStation MRI (See pages 8 - 13)

Section A) Perfusor Space Infusion Syringe Pump

A01) Proposed Device

Trade/Proprietary Name:	Perfusor® Space Infusion Syringe Pump
Common/Usual Name:	Infusion Syringe Pump
Regulation Number:	880.5725
Regulation Device:	Infusion Pump
Product Code:	FRN
Device Class:	Class II
Classification Panel:	General Hospital

A02) Legally Marketed Predicate Device

Perfusor® Space Infusion Syringe Pump System by B. Braun Melsungen AG - K062699

A03) Device Description

The Perfusor® Space Infusion Syringe Pump is a 12V DC or battery powered external, transportable, infusion syringe pump. The Perfusor® Space Infusion Syringe Pump utilizes a swivel-drive pumping mechanism and is intended to provide infusions of parenteral and enteral fluids. The Perfusor® Space Infusion Syringe Pump is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments (only road ambulances). A trained Biomedical Technician must perform a complete set-up of the pump prior to use in a clinical setting.

The system is intended to provide intermittent or continuous delivery of parenteral and enteral fluids to the patient. Parenteral fluids may include all standard fluids and/or medications indicated for infusion as well as blood and blood products.

The Perfusor® Space Infusion Syringe Pump uses standard, single-use, disposable syringes (with luer-lock connectors) designed for use on syringe pumps and validated on the Perfusor® Space Infusion Syringe Pump.

A04) Indications for Use Statement

The Perfusor® Space Infusion Syringe Pump System includes an external transportable electronic infusion syringe pump and pump accessories. The system is 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 system is 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 Perfusor® Space Infusion Syringe Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments (only road ambulances).

A05) Substantial Equivalence Discussion

The Perfusor Space Infusion Syringe Pump design and functional characteristics are the same as those cleared under K062699. The labeling was revised to indicate that the pump is MRI Conditional when

used within the SpaceStation MRI. The only changes to the Perfusor Space Infusion Syringe Pump are the following:

Table 5A – Comparison of Changed Characteristics

Characteristic	**Subject Device K191910** Perfusor Space Infusion Syringe Pump	**Predicate Device K062699** Perfusor Space Infusion Syringe Pump System	**Discussion of Differences**
MRI Compatibility	MRI Conditional - only within the SpaceStation MRI. The device is MRI Unsafe if used as a standalone device.	MRI Unsafe	There is no change to the subject infusion pump device, only the change to the environment of use when the subject device is used within the SpaceStation MRI. Performance in an MR environment was verified and validated.
Additional Labeling	MRI Conditional when used within SpaceStation MRI. Provides reference to SpaceStation MRI labeling.	MRI Unsafe	There is no change to the subject infusion pump device, only the change to the environment of use when the subject device is used within the SpaceStation MRI. The additional labeling describes the MRI conditional use of the subject device.

The subject device and the predicate device are both infusion pumps; the same in design and functional characteristics. The labeling of the subject device is being revised to indicate that the subject device is MRI Conditional when used within the SpaceStation MRI. The functionality of the Pefusor Space Infusion Syringe Pump was verified when used in the SpaceStation MRI in MR conditions by verification testing.

A06) Non-Clinical Performance Data

Testing was performed to verify the proper functioning of the Perfusor Space Infusion Syringe Pump in the intended Magnetic Resonance (MR) environment when used with the SpaceStation MRI. Both, the influence of the Perfusor Space Infusion Syringe Pump (within the SpaceStation MRI) on the functioning of the intended MRI Scanners and the influence of the intended MRI Scanners on the functioning of the Perfusor Space Infusion Syringe Pump (within the SpaceStation MRI) were tested.

The following functional testing/compatibility testing was completed to demonstrate substantial equivalence of the Perfusor Space Infusion Syringe Pump to the predicate device when used in the SpaceStation MRI in the intended MR environment. The pre-determined acceptance criteria was met in all testing.

Device performance in intended MR Conditions with SpaceStation MRI	• The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle", Including flow rate/bolus accuracy, alarm verifiction, etc.
MRI compatibility	• MR Compatibility testing described in Section C06) for the SpaceStation MRI was completed with Perfusor Space Infusion Syringe Pumps within the SpaceStation MRI

No clinical testing was completed to support substantial equivalence of the subject device to the predicate device.

A07) Statement of Substantial Equivalence

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The Perfusor Space Infusion Syringe Pump is Substantially Equivalent (SE) to the Perfusor Space Infusion Syringe Pump System, cleared under K062699.

Section B) Infusomat Space Volumetric Infusion Pump

B01) Proposed Device

Trade/Proprietary Name:	Infusomat® Space Volumetric Infusion Pump
Common/Usual Name:	Volumetric Infusion Pumps (Syringe and Volumetric Pumps)
Regulation Device:	Pump, Infusion
Regulation Number:	880.5725
Product Code:	FRN
Device Class:	Class II
Classification Panel:	General Hospital

B02) Legally Marketed Predicate Device

Infusomat® Space Volumetric Infusion Pump System by B. Braun Melsungen AG - K062700

B03) Device Description

The Infusomat Space Volumetric Infusion Pump is a 12V DC or battery powered external, transportable, volumetric infusion pump. The Infusomat Space Volumetric Infusion Pump utilizes a linear peristaltic pumping mechanism and is intended to provide infusions of parenteral and enteral fluids. The lnfusomat Space Volumetric Infusion Pump is intended for but not limited to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments (only road ambulances). A trained Biomedical Technician must perform a complete set-up of the pump prior to use in a clinical setting.

The system created by using the administration sets with the Infusomat Space Volumetric Infusion Pump is intended to provide intermittent or continuous flow of parenteral and enteral fluids to the patient. Parenteral fluids may include all standard fluids and/or medications indicated for infusion as well as blood and blood products.

B04) Indications for Use Statement

The Infusomat® Space Volumetric Infusion Pump System includes an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories. The system is 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, irrigation/ablation, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to colloids and cristalloids, blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments. (only road ambulances).

B05) Substantial Equivalence Discussion

The Infusomat Space Volumetric Infusion Pump design and functional characteristics are the same as those cleared under K062700. The labeling was revised to indicate that the pump is MRI Conditional when used within the SpaceStation MRI. The only changes to the Infusomat Space Volumetric Infusion Pump are the following:

Table 5B – Comparison of Changed Characteristics

Characteristic	**Subject Device K191910** Infusomat® Space Volumetric Infusion Pump	**Predicate Device K062700** Infusomat® Space Volumetric Infusion Pump System	**Discussion of Differences**
MRI Compatibility	MRI Conditional - only within the SpaceStation MRI. The device is MRI Unsafe if used as a standalone device.	MRI Unsafe	There is no change to the subject infusion pump device, only the change to the environment of use when the subject device is used within the SpaceStation MRI. Performance in an MR environment of use was verified and validated.
Additional Labeling	MRI Conditional when used within SpaceStation MRI. Provides reference to SpaceStation MRI labeling.	MRI Unsafe	There is no change to the subject infusion pump device, only the change to the environment of use when the subject device is used within the SpaceStation MRI. The additional labeling describe the MRI conditional use of the subject device

The subject device and the predicate device are both infusion pumps; the same in design and functional characteristics. The labeling of the subject device is being revised to indicate that the subject device is MRI Conditional when used within the SpaceStation MRI. The functionality of the Infusomat Space Volumetric Infusion Pump was verified when used in the SpaceStation MRI in MR conditions by verification testing.

B06) Non-Clinical Performance Data

Testing was performed to verify the proper functioning of the Infusomat Space Volumetric Infusion Pump in the intended Magnetic Resonance (MR) environment when used with the SpaceStation MRI. Both, the influence of the Infusomat Space Volumetric Infusion Pump (within the SpaceStation MRI) on the functioning of the intended MRI Scanners and the influence of the intended MRI Scanners on the functioning of the Infusomat Space Volumetric Infusion Pump (within the SpaceStation MRI) were tested.

The following functional testing/compatibility testing was completed to demonstrate substantial equivalence of the Infusomat Space Volumetric Infusion Pump to the predicate device when used in the SpaceStation MRI in the intended MR environment. The pre-determined acceptance criteria was met in all testing.

Device performance in intended MR Conditions with SpaceStation MRI	• The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle", Including flow rate/bolus accuracy, alarm verifiction, etc.
MRI compatibility	• MR Compatibility testing described in Section C06) for the SpaceStation MRI was completed with Perfusor Space Infusion Syringe Pumps within the SpaceStation MRI

No clinical testing was completed to support substantial equivalence of the subject device to the predicate device.

B07) Statement of Substantial Equivalence

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The Infusomat Space Volumetric Infusion Pump is Substantially Equivalent (SE) to the Infusomat Space Volumetric Infusion Pump System, cleared under K062700.

Section C) Traditional 510(k) SpaceStation MRI

C01) Proposed Device

Trade/Proprietary Name:	SpaceStation MRI
Common/Usual Name:	MRI System Rack for B. Braun Space Infusion Pumps (Perfusor Syringe and Infusomat Volumetric Pumps)
Regulation Device:	Accessories, Pump, Infusion
Regulation Number:	880.5725
Product Code:	MRZ
Device Class:	Class II
Classification Panel:	General Hospital

C02) Legally Marketed Predicate Device(s)

MRI-Caddy (MIPM Mammendorfer Institut für Physik und Medizin GmbH) - K030323

C03) Device Description

The SpaceStation MRI is a movable MRI Rack System for the operation of up to four B.Braun Space Infusions Pumps in MRI rooms (faraday cage of antimagnetic materials) during MRI examinations of patients. The SpaceStation MRI does not include the Infusion Pumps, and it does not control the operation of the user-installed Infusion Pumps. Patients are moved from nursing units to the MRI area with infusing pumps which are placed in the SpaceStation MRI for the MRI scan.

The SpaceStation MRI is a RF-shielded housing which is mounted on the trolley. The mechanical construction of the housing makes it possible to position the system within the MRI room; it provides a shielded space and mechanical and electrical connections for up to four Space Infusion Pumps. A window in the door allows for direct viewing of the inserted infusion pumps, allowing all pump status and alarm conditions to be observed. The exterior housing provides IV line inlets and outlets, and knobs to release the infusion pumps.

The SpaceStation MRI (Unit) includes the SpaceStation with SpaceCover comfort and Magnet Indicator Tesla Spy 2010.

The SpaceCover comfort includes a large light display that shows the status and alarm condition of the pumps within the station as well as an audible alarm.

The Magnet Indicator Tesla Spy 2010 allows the operator to correctly position the SpaceStation MRI within the MRI room by measurement of the magnetic flux density. An optical and audible alarm is triggered if the station is too close to the MRI, exceeding the permitted flux density.
The Trolley has an IV pole and provides a mount for the Safety Tether. The SpaceStation MRI is not connected to a network.

C04) Indications for Use Statement

The SpaceStation MRI is a MRI (Magnetic Resonance Imaging) System Rack for the operation of Space Infusion Pumps during MRI examinations (MRI procedures) of adult, pediatric or neonatal patients.

The product is intended to be used by qualified healthcare professionals.

C05) Substantial Equivalence Discussion

The following Table 5C compares the SpaceStation MRI to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Table 5C – Comparison of Characteristics- SpaceStation MRI

Characteristic	Subject Device K191910 B. Braun Melsungen AG SpaceStation MRI	Predicate Device K030323 MIPM MRI-Caddy	Discussion of Differences
Regulation Number	880.5725	880.5725	No difference
Regulation Description	Infusion pump.	Infusion pump.	No difference
Device Product Code	Accessories, Pump, Infusion MRZ	Pump, Infusion FRN	Both devices have the same environment of use. The predicate device includes fixed infusion pumps in the MRI systems rack, whereas with the subject device, the user has the ability to add or remove infusion pumps. Performance of the Space pumps within the SpaceStation MRI was verified and validated for use in the MR environment.
Indications for Use	The SpaceStation MRI is a MRI (Magnetic Resonance Imaging) System Rack for operation of Space Infusion Pumps during MRI examinations (MRI procedures) of adult, pediatric or neonatal patients. The product is intended to be used by qualified healthcare professionals.	The intended medical application of MRI-Caddy with three 2000-Series syringe pumps is to produce controlled movement of the plunger of a syringe to inject a set amount of therapeutic fluid into a patient within a hospital setting at a set rate and at set times. The MRI-Caddy is designed for use in an MR-environment at a maximum magnetic field strength of 20mT.	Both devices have the same environment of use. The predicate device includes fixed infusion pumps in the MRI systems rack, whereas with the subject device, the user has the ability to add or remove infusion pumps. Performance of the Space pumps within the SpaceStation MRI was verified and validated for use in the MR environment.

Characteristic	Subject Device K191910 B. Braun Melsungen AG SpaceStation MRI	Predicate Device K030323 MIPM MRI-Caddy	Discussion of Differences
Type of unit	MRI system rack, including SpaceStation, SpaceCover comfort (housing up to 4 B. Braun Infusomat Space Volumetric and Perfusor Space Syringe infusion pumps)	MRI systems rack, designed for using Medex 2010 pumps (fixed in the MRI-Caddy housing, up to 3 pumps)	Both devices are MRI system racks that allow infusion pumps to be used within the MR environment. The difference is the physical pump that the MRI system rack was designed to contain. Performance of the B. Braun Space pumps within the SpaceStation MRI was verified and validated in the MR environment
Includes Infusion Pumps as a part of 510(k) clearance	No	Yes	The predicate device includes fixed infusion pumps in the MRI systems rack. With the subject device, the user has the ability to add or remove Space Infusion Pumps. Performance of the Space pumps within the SpaceStation MRI was verified and validated for use in the MR environment.
Includes Status and Alarm display	Yes	Yes (Central alarm)	No difference
Includes Magnetic flux density indicator (Tesla Spy 2010)	Yes	No	The predicate device instructions state to position the device at a certain location within the MR environment. The subject device instructions state the same but the device also uses a magnetic flux density indicator to notify the operator of a correctly positioned device. Performance of the magnetic flux density indicator was verified and validated.
MRI Conditional	Yes	Yes	No difference
Mode of operation	Continuous	Continuous	No difference

Characteristic	Subject Device K191910 B. Braun Melsungen AG SpaceStation MRI	Predicate Device K030323 MIPM MRI-Caddy	Discussion of Differences
AC Powered	100 to 240 VAC, 50/60 Hz	100 to 240 VAC, 50/60 Hz	No difference
Network Connection	No	No	No difference
Sterile	No	No	No difference
Single-Use	No	No	No difference
Latex Free	Yes	Yes	No difference
MRI Safety and Compatibility tests	Yes 1.5 Tesla and 3 Tesla	Yes 1.5 Tesla and 3 Tesla	No difference

The subject and the predicate devices are both mobile infusion pump management systems to accommodate dedicated infusion pumps. The SpaceStation MRI and the predicate MRI-Caddy both have a faraday cage of antimagnetic materials, which allows them to operate within specification in a MR environment up to 20mT.

The SpaceStation MRI differs from the predicate by having a magnetic flux density indicator (Tesla Spy 2010), which helps the user to correctly position the subject device within the MRI room by measuring the magnetic flux density. The functionality of the Tesla Spy 2010 with the SpaceStation MRI system is verified by performance testing.

The MRI Caddy provides one red light for main alarm indication, whereas the SpaceStation MRI comes with a Status and Alarm display (SpaceCover comfort), all status and alarm conditions within the system as well of as of the pumps themselves are signalized. The functionality of these alarm systems were verified by performance testing.

Based on the information described within this section, the subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

C06) Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of SpaceStation MRI and in showing substantial equivalence to the predicate device. B. Braun Melsungen AG completed a number of non-clinical performance tests.

The SpaceStation MRI passed all testing in accordance with internal requirements, national standards, and international standards shown above to support substantial equivalence of the subject device:

Extensive tests were performed to verify the proper functioning of the SpaceStation MRI in the intended Magnetic Resonance (MR) environment. Both, the influence of the SpaceStation MRI on the functioning of the intended MRI Scanners and the influence of the intended MRI Scanners on the functioning of the SpaceStation MRI were tested. Human factors testing of the SpaceStation MRI was completed to validate safe and proper use of the device.

A summary of the performance data/non-clinical testing that was provided in support of the substantial equivalence determination for the SpaceStation MRI is provided below:

Table 5D – Performance Testing Summary

Software	Software of SpaceStation MRI components, SpaceCover Comfort and Magnet Indicator Tesla Spy 2010 were verified/validated in the following ways: • Software documentation is included according to FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for Major level of concern for the software embedded in the SpaceStation MRI System. • Software validation was conducted according to FDA guidance document General Principles of Software Validation – Final Guidance for Industry and FDA Staff.
Electrical Safety	• AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R) 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EMC	• IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for basic Safety and essential performance - Collateral Standard: Electromagnetic Disturbances -Requirements and Tests
MRI compatibility	• Measurement of magnetostatic forces in accordance with intended MR conditions • Magnetic immunity in accordance with intended MR conditions • MRI immunity in accordance with intended MR conditions • Radio frequency field induced and gradient field induced heating con • Field interference test in accordance with FDA recognized standard ASTM F2119: 2013 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
Device Functionality/Compatibility Testing	• Verification of SpaceStation MRI – Magnetic Indicator/Tesla spy 2010 functionality and associated alarm detection system • The essential performance requirements of the compatible Perfusor and Infusomat pumps were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle", including flow rate/bolus accuracy, alarm verifiction, etc., while used with SpaceStation MRI when used in accordance with intended MR conditions.
Human Factors	• Human factors studies per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human factors studies were conducted with the intended user population, use environment and use scenarios to simulate clinical

	conditions. Results of the human factors testing demonstrate validation of the device per the intended use. • Human factors study was conducted in alignment with FDA recognized standard: IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices.
Risk Management	• A risk analysis was conducted in accordance with FDA recognized standard ISO 14971: 2007 Medical devices - Application of risk management to medical devices.

No clinical testing was completed to support substantial equivalence of the subject device to the predicate device.

C07) Statement of Substantial Equivalence

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The SpaceStation MRI is Substantially Equivalent (SE) to the MRI-Caddy, cleared under K030323.