June 12, 2018

B.Braun Medical Inc  
Tracy Maddock  
Sr. Regulatory Affairs Specialist  
901 Marcon Blvd  
Allentown, Pennsylvania 18109  

Re: K172831  
Trade/Device Name: Perfusor® Space Syringe Infusion Pump System  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: Class II  
Product Code: FRN, LZH  
Dated: May 30, 2018  
Received: May 30, 2018

Dear Tracy Maddock:

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. 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); good
manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
Perfusor® Space Syringe Infusion Pump System

Indications for Use (Describe)
The Perfusor® Space Syringe Infusion Pump System is intended for use on adults, pediatrics and neonates for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, epidural and enteral.

The Perfusor® Space Syringe Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities and for medical ground and/or air transport situations.

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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Preparation Date: June 8, 2018

Manufacturer's Name: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
Establishment Registration 2523676

Corresponding Official: Primary Contact: Tracy Maddock
Sr. Regulatory Affairs Specialist

Telephone Number: (610)-596-2545
Fax Number: (610)-266-4962
E-mail Address: tracy.maddock@bbraunusa.com

Trade Name: Perfusor® Space Syringe Infusion Pump System

Common or Usual Name: Infusion Pump
Regulation Name: Infusion Pump
Regulation Number: 21 CFR 880.5725
Product Code: FRN, pump, infusion
LZH, pump, infusion, enteral
Device Class: Class II

Primary Predicate Device: K092313, Perfusor® Space Syringe Infusion Pump System
Secondary Predicate Device: K062699, Perfusor® Space Syringe Infusion Pump System

Reference Device K142596, B. Braun Infusomat Space Volumetric Infusion Pump System

Device Description
The Perfusor® Space Syringe Infusion Pump System includes an external, transportable, electronic infusion pump and pump accessories.

The Perfusor® Space Syringe Infusion Pump utilizes a swivel drive pumping mechanism and operates on a 12V DC power source that can be provided from a battery or through external sources such as a power supply connected to a 120V AC wall outlet.

The front panel of the Perfusor® Space Pump includes a backlit graphical display, a backlit keypad with 10 push buttons including directional arrows to navigate through menu items and program values, and indicator lamps to alert the clinician to critical conditions.

The Perfusor® Space Syringe Infusion Pump is capable of wireless communication both inbound and outbound. Autoprogramming of the pump is possible where the pump receives infusion parameters wirelessly from the electronic health record over the hospital Wireless Local Access Network.

The B. Braun Space Station is a flexible docking and communication system designed to accommodate multiple Perfusor® Space Syringe Infusion Pumps for use in a medical facility.
**SpaceCom** is a communication device that has been integrated into the SpaceStation. SpaceCom supports different interfaces such as Ethernet, PS2-Keyboard, Serial, USB ports and WLAN network card. Data transfer with the pumps is provided via an internal CAN bus. The pumps are coupled together with connectors on the inner backside of the SpaceStation. These connectors provide the voltage supply, distribute the information in the Space system via a serial interface, transfer data via a bus system (CAN bus) and transmit a staff call, which may be pending. Features like barcoding and wireless data transmission are enabled when a Perfusor® Space Pump is housed within a SpaceStation with SpaceCom. The outbound data communication through SpaceCom transfers status data of the infusion pumps to a hospital server.

**Space OnlineSuite** is a server based software system which provides the following applications:

- **Space Server Core** is the basic server framework for Space applications. This application framework provides basic server functions like User Management, License Management, Data Management, Communication Service, Security and Maintenance Functions. These functions are used by the administrator of the Space OnlineSuite. Drug Library Manager and Upload Manager applications also use the basic functions of SpaceServer Core.

- **Drug Library Manager** is used to create and administer a drug library which can be used in the Perfusor® Space Syringe Infusion Pump. These features are designed to enhance medication safety and reduce medication errors.

- **Upload Manager** can be used to manage the upload of drug libraries to any single B. Braun Space infusion pump, multiple Space pumps within a facility or to all Space pumps on the System. The drug libraries will be uploaded to SpaceCom (within SpaceStation) and then transferred via CAN bus (Controller Area Network) to the pumps or to a single Perfusor® Space Syringe Infusion Pump directly.

**Indications for Use**

The Perfusor® Space Syringe Infusion Pump System is intended for use on adults, pediatrics and neonates for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, epidural and enteral.

The Perfusor® Space Syringe Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities and for medical ground and/or air transport situations.

The device is prescription only.

**Intended Use**

Intended population: adults, pediatrics and neonates.

Intended environment: healthcare facilities, medical ground and/or air transport
**Substantial Equivalence Discussion**

**Indications for Use Comparison**

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th><strong>Subject Device</strong></th>
<th><strong>Predicate Device</strong></th>
<th><strong>Predicate Device</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>K172831</td>
<td>K092313</td>
<td>K062699</td>
</tr>
<tr>
<td></td>
<td>Perfusor® Space Syringe Infusion Pump System</td>
<td>B. Braun Perfusor® Space Syringe Infusion Pump System</td>
<td>B. Braun Perfusor® Space Syringe Infusion Pump System</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The Perfusor® Space Syringe Infusion Pump System is intended for use on adults, pediatrics and neonates for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, epidural and enteral. The Perfusor® Space Syringe Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities and for medical ground and/or air transport situations.</td>
<td>The Perfusor Space Infusion Syringe pump System is an electrical, external, syringe infusion pump system indicated for use with adults, pediatrics and neonates and is intended to provide infusions of parenteral fluids/medications, blood and blood products indicated for infusion through FDA approved routes of administration.</td>
<td>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, anticoagulations, 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).</td>
</tr>
<tr>
<td><strong>Prescription Only or Over the Counter</strong></td>
<td>Rx Only</td>
<td>Rx Only</td>
<td>Rx Only</td>
</tr>
<tr>
<td><strong>Intended Population</strong></td>
<td>Adults, pediatrics, neonates</td>
<td>Adults, pediatrics, neonates</td>
<td>Adults, pediatrics, neonates</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>Healthcare facilities and medical transport environments (ground and air)</td>
<td>Healthcare facilities, home care, outpatient and medical transport environments (only road ambulances)</td>
<td>Healthcare facilities and medical transport environments (only road ambulances)</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
</tbody>
</table>

**Discussions of differences in Indications for Use statement**
The subject device and the predicate device have the same users and environments of use. The subject device also has the same intended use (intended for the delivery of fluids, medications, blood and blood products) as the predicate devices. The patient population (adult, pediatrics, and neonates) is the same for the proposed and predicate devices. The routes of administration, intravenous, intra-arterial, epidural and subcutaneous were cleared in both predicate devices. Enteral administration of fluids was cleared through the Perfusor® Space Syringe Infusion Pump System, K062699 submission. The indications for use statements are substantially equivalent.

**Discussions of differences in intended population**
The intended population for the subject device is identical to the predicate devices.

**Discussions of differences in environment of use**
The environment of use for the subject device is similar to the predicate devices with the addition of air transport.

**Technological Characteristics**
B. Braun Perfusor® Space Syringe Infusion Pump System has the same intended use (intended for the delivery of fluids, medications, blood and blood products) and the same principle of operation as the predicate devices. The patient population (adult, pediatrics, and neonates) is the same for the proposed and predicate devices. The routes of administration, intravenous, intra-arterial, epidural and subcutaneous were cleared in both predicate devices. Enteral administration of fluids was cleared through the Perfusor Space Syringe Infusion Pump System, K062699 submission. The proposed infusion pump is the same design as the predicate with respect to materials of construction (injection molded thermoplastic) and have the same hardware interface. The mechanics of the Perfusor® Space Syringe Infusion Pump System has not changed since the original submission (K062699).

The difference between proposed and predicate devices is an updated version of software. The B. Braun Perfusor® Space Syringe Infusion Pump includes software version U whereas the predicate device (K092313) utilized software version G. Changes to the software included the addition of new features such as Dose over Time and autoprogramming, modifications to the user interface, additional dosing units, modified barcode functionality, Drug Library modifications and upload utilizing wireless communication, and a new Li-ion battery pack with wireless communication.

The new software has been subjected to verification and validation testing. Changes to the software which impacted the user interface were validated through Human Factors testing.
The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

<table>
<thead>
<tr>
<th>Technological Characteristic</th>
<th>Subject Device K172831 Per fusor® Space Syringe Infusion Pump System</th>
<th>Predicate Device K092313 B. Braun Per fusor® Space Syringe Infusion Pump System</th>
<th>Predicate Device K062699 B. Braun Per fusor® Space Syringe Infusion Pump System</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Pump</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Infusion Type</td>
<td>Parenteral / Enteral</td>
<td>Parenteral</td>
<td>Same</td>
<td>discussion below</td>
</tr>
<tr>
<td>Pump Mechanism</td>
<td>Swivel Drive</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Power Supply</td>
<td>100 - 240 V AC, 50/60Hz rechargeable Li-ion/rechargeable NiMH Battery 12 V adapter</td>
<td>100 - 240 V AC, 50/60Hz rechargeable NiMH Battery 12 V adapter</td>
<td>100 - 240 V AC, 50/60Hz rechargeable NiMH Battery 12 V adapter</td>
<td>discussion below</td>
</tr>
<tr>
<td>Battery Pack</td>
<td>Li-ion / NiMH</td>
<td>NiMH</td>
<td>NiMH</td>
<td>discussion below</td>
</tr>
<tr>
<td>Battery Cells</td>
<td>Two cells - 1400 mAh (Li-Ion) Four cells - 1800 mAh (NiMH)</td>
<td>Four 1800 - mAh</td>
<td>Four 1800 - mAh</td>
<td>discussion below</td>
</tr>
<tr>
<td>Recharge Time</td>
<td>Approx. 6 hours for 100% capacity</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Battery Run Time</td>
<td>Approx. 8 hours at 25 ml/hr</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Battery Electronics</td>
<td>Processor PCB monitors and controls battery charge, discharge, and temperature with embedded battery maintenance software</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>User Interface</td>
<td>Backlit Cursor Navigation</td>
<td>Similar</td>
<td>Similar</td>
<td>discussion below</td>
</tr>
<tr>
<td>Keypad</td>
<td>Non-numeric navigation keys Matrix configuration</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Visual Display</td>
<td>Backlit Graphic Digital LCD</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Syringe Selection</td>
<td>Syringe holder selects size and displays possible syringes from a look up table</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Compatible syringes (in mL)</td>
<td>B. Braun 3, 5, 10, 20, 30, 50 Monoject (Covidien) 3, 6, 12, 20, 35, 60 BD 3, 5, 10, 20, 30, 60 NeoMed 3, 6, 12, 20, 35, 60</td>
<td>B. Braun 2, 5, 10, 20, 30, 50 Monoject (Tyco) 3, 6, 12, 20, 35, 50/60 BD 3, 5, 10, 20, 30, 50/60 Terumo 3, 5, 10, 20, 30, 60</td>
<td>Monoject (Tyco)3, 6, 12, 20, 35, 50/60 BD 3, 5, 10, 20, 30, 50/60 Terumo 3, 5, 10, 20, 30, 60</td>
<td>discussion below</td>
</tr>
<tr>
<td>Micro-processor</td>
<td>Renesas Electronics Corporation Dual processors Functional (FμP)</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Feature</td>
<td>FμP - I-Logix Rhapsody</td>
<td>KμP - Hitachi IDE</td>
<td>C/C++</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td><strong>Program language</strong></td>
<td>FμP</td>
<td>KμP</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Operating system</strong></td>
<td>EMBOSS</td>
<td>CMX</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Volume increments</strong></td>
<td>0.1 - 99.99 ml (increments of 0.01 ml)</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 - 999 ml (increments of 0.1 ml)</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1000 - 9999 ml (increments of 1 ml)</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Rate increments</strong></td>
<td>0.01 - 99.99 ml/hr in increments of 0.01 ml/hr</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 - 999 ml/h in increments of 0.1 ml/hr</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Delivery Rate Accuracy</strong></td>
<td>± 2% according to IEC/EN 60601-2-24</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Pump Connectivity</strong></td>
<td>WLAN adapter 802.11 a/b/g/n, Encoding: WEP, WPA, Encryption: WEP-128, TKIP, Authentication: Open shared, WPA, WPAPSK, USB 2.0 - CAN bus via computer</td>
<td>USB 2.0 - CAN bus via computer</td>
<td>USB 2.0 - CAN bus via computer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discussion below</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Drug Library</strong></td>
<td>1200 drug names, 50 care units, 16 patient profiles, 30 drug categories</td>
<td>1500 drug names, 1 care area, 1 patient profile, 15 drug categories</td>
<td>720 drug names, 15 categories</td>
<td></td>
</tr>
<tr>
<td><strong>Dosing Limits</strong></td>
<td>soft and hard limits</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Dosing Units</strong></td>
<td>gram, milli gram, micro gram, nano gram, unit, milli unit, kilo unit, million unit, milli equivalent, milli mole, kilo calorie, milli liter, kilo gram, meters squared, minutes, hour</td>
<td>gram, milligram, microgram, units, milli units, pound, gram, kilogram, units / square meter, minute, hours, day</td>
<td>gram, milligram, microgram, units, milli units, pound, gram, kilogram, units / square meter, minute, hours, day</td>
<td></td>
</tr>
<tr>
<td><strong>Dose Over Time therapy</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>Bolus capabilities</strong></td>
<td>Yes</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td><strong>Auto programming</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>Barcoding capability</strong></td>
<td>Digital imager – reads 1D and 2D images</td>
<td>Same</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Pump History File</strong></td>
<td>Last 1000 Entries</td>
<td>Last 1000 Events</td>
<td>Last 1000 Events</td>
<td></td>
</tr>
<tr>
<td><strong>Wireless LAN pump</strong></td>
<td>WLAN adapter 802.11 a/b/g/n, Encoding: WEP, WPA Encryption: WEP-128, TKIP Authentication: Open shared, WPA, WPAPSK</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Shock Protection</strong></td>
<td>Defibrillation-protected Type CF protection rating II Protection rating I in</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
</tbody>
</table>

**Discussion below**: Additional information or notes related to the highlighted features.
<table>
<thead>
<tr>
<th><strong>Moisture Protection</strong></th>
<th>IP22</th>
<th>Same</th>
<th>Same</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td>Approx. 3.1 lbs. - 1.4 kg</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Approx. 9.8 x 2.6 x 5.9 inches</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Operating Conditions</strong></td>
<td><strong>Relative humidity:</strong> 30% - 90% (without condensation), <strong>Temperature:</strong> 5°C - 40°C (41°F – 105°F), <strong>Atmospheric pressure:</strong> 500 mbar -1060 mbar (7.25 – 15.37 psi)</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Space Station**

<table>
<thead>
<tr>
<th><strong>Space Station</strong></th>
<th>Docking unit for up to 4 Space pumps. Provides power and CAN bus communications to connected Space pumps</th>
<th>Same</th>
<th>Same</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power Supply</strong></td>
<td>100 - 240 V AC 50/60Hz NiMH Battery</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Barcoding</strong></td>
<td>Clinician ID, Patient ID, Medication - Patient Confirmation, Program Infusion Therapy with Confirmation</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Expandability</strong></td>
<td>Tool free assembly, Up to 6 Space Stations Configured in one, two, or three columns</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Fixation</strong></td>
<td>Universal Clamp to attach to Infusion pole or horizontal wall rail system</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Communication Interface</strong></td>
<td>Space Com II USB communication</td>
<td>Space Com</td>
<td>N/A</td>
<td>discussion below</td>
</tr>
<tr>
<td><strong>Connectivity</strong></td>
<td>Serial RS 232, PS2, Ethernet RJ45, USB</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Wireless LAN</strong></td>
<td>USB WLAN adapter 802.11 a/b/g/n, Encoding: WEP, WPA Encryption: WEP-128, TKIP Authentication: Open shared, WPA, WPA-PSK</td>
<td>Compact Flash WLAN adapter 802.11 a/b/g, Encoding: WEP, WPA Encryption: WEP-128, TKIP Authentication: Open shared, WPA, WPA-PSK</td>
<td>N/A</td>
<td>discussion below</td>
</tr>
</tbody>
</table>

*Discussions of differences in technological characteristics*

**Infusion Type:** The subject device is intended for parenteral and enteral delivery of fluids, medications, blood and blood products while K092313 is only indicated for parenteral delivery. The second predicate is intended for both parenteral and enteral delivery, the same as the subject device. The differences in the routes of administration between enteral and parenteral do not raise different questions of safety or effectiveness and the subject device has been verified and validated through performance testing to meet its intended use.
**Power Supply, Battery Pack, Battery Cells:** The subject Perfusor Infusion Pump and the predicate devices all include a plug-in power supply, rechargeable NiMH battery, and 12 V adapter. In addition, the subject device includes an optional rechargeable Li-ion (Lithium-Ion) battery. This difference does not raise different questions of safety and effectiveness. The Li-ion and the NiMH rechargeable batteries have different chemistries but provide similar performance and function in the same way, to provide operation independent from AC power during transport situations or interruptions of the voltage supply. The specific testing used to validate the difference in the battery was provided. Testing also demonstrated that the power supply and battery pack function so that the device meets its intended use.

**Compatible syringes (in mL):** The differences in the compatible syringes are limited to manufacturer. The size of compatible syringes has not changed and therefore the differences are still substantially equivalent. Performance data confirms that the syringes are compatible.

**Drug Library:** The Drug Library Manager is the software program used to create a drug pool with drug names and corresponding parameters. The differences in the number of drug names, care units, patient profiles, and drug categories between the subject device and the predicates do not impact the core technology of the Drug Library. The Drug Library was subjected to verification and validation testing which supports the intended use.

**Dosing Units:** Additional measurement units common to medical practitioners were added to the pump to provide flexibility when inputting drug doses and flow rates. The differences in dosing units between the subject device and the predicate devices do not impact the core technology of the pump and therefore the dosing units are substantially equivalent.

**Dose Over Time therapy:** Dose over time is a new feature to the Perfusor Space Syringe Infusion Pump System that allows the pump to administer a specific dose of medication in a specific time. This feature was verified and validated as part of the system performance testing. The new dose over time feature does not raise different questions of safety or effectiveness.

**Auto programming:** Auto programming is a new feature to the Perfusor Space Syringe Infusion Pump System that allows the pump to be auto programmed by reducing the manually necessary programming steps by the user. The infusion parameters are received by the pump from an Electronic Health Record System and needs to be verified with the physician prescription by the user at the pump interface. This feature was verified and validated as part of the system performance testing. The auto programming feature does not raise different questions of safety or effectiveness.

**Barcoding capability:** Barcode functionality was modified to allow more flexibility in how a barcode is distributed to the pumps. The former software had SpaceCom distribute the scanned clinician and patient ID barcode to all infusion pumps within a SpaceStation. The new software allows the facility to configure SpaceCom to distribute the scanned clinician and/or patient ID to an individual pump. A re-scan is required to distribute the ID(s) to the other pumps as needed. The modified barcode functionality supports the new dosing units and the new drug library functionality. This modification was verified and validated for the intended use.

**Pump History File:** The differences between entries and events for recording in the pump history file capture the same critical information and therefore are substantially equivalent.

**Pump User Interface and Space Station Communication Interface:** Modifications of the user interface were made by changing the graphical user interface (GUI) display. Types of modifications to the GUI included modifications to: menu navigation, display terminology, warning prompts, improve workflows, and to include
additional pictograms. Modifications were also made to the time unit entry and the syringe loading process. These modifications were validated through the human factors summative testing.

**Pump Connectivity, Wireless LAN pump and Wireless LAN Space Station:** Connectivity of the subject Perfusor Infusion Pump and the predicate devices is accomplished through the USB 2.0 – CAN bus via computer. The CAN bus interface is a wired channel used to connect a PC to the pump for purposes of performing maintenance, Drug Library upload and parameter configuration. Both the subject and predicate Perfusor Infusion pump communicate via Space Station and included SpaceCom board. This connectivity provides communication with the pump for both wired and wireless Drug Library upload and transmission of operating data to and from external sources. In addition, wireless connectivity is optionally available for the subject Perfusor Space Pump by using the Li-Ion Battery Pack. Pump-based wireless communication is made possible by a wireless card included in the Li-ion battery pack. The optional Li-ion battery with WiFi represents an additional channel of communication with the subject pump for wireless Drug Library upload and transmission of operating data to and from external sources. The wireless operation mode incorporates radio-frequency wireless technology 802.11 a/b/g/n, utilizing two frequency ranges 2.4 GHz band and 5 GHz. The methods used to verify and validate the wireless connectivity are the same as those used in the reference device, the B. Braun Infusomat Space Volumetric Infusion Pump System cleared through K142596. This difference does not raise different questions of safety and effectiveness. The essential performance of the pump is not influenced by the wireless communication interface. While inbound communication capability has been added to the subject pump, the clinician must still accept the order, confirm all infusion parameters, and confirm the order at the pump prior to infusion. Pump operation with and without WiFi enabled has been demonstrated through specific performance testing.

The differences between subject device and predicate devices do not raise any different issues of safety and effectiveness and have been adequately verified and validated to meet the intended use of the device.

**Performance Testing**

A safety assurance case was provided for the Perfusor® Space System Syringe Pump, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The stated goal of the safety assurance case is:

- The B Braun Perfusor® Space infusion system is adequately safe for its intended use

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments covered the following attributes:

- Residual risks are analyzed and determined to be acceptable
- The device meets clinically valid essential performance specifications
  - Delivery Accuracy
  - Pressure Limitation
  - Post Occlusion Bolus Protection
  - High Priority Alarms
- The B Braun Perfusor® Space infusion system is adequately reliable to ensure safety over device use life.

The following specific evidence was included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices:

- Software verification and validation per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) for a Major Level of Concern
- Cybersecurity of the Perfusor® Space Syringe Infusion Pump System was evaluated per the FDA Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry
and Food and Drug Administration Staff, (October 2, 2014). Specifically, addressing the following areas: Identify and Protect, Detect, Response and Recover

- System verification and validation demonstrated that design inputs were met including:
  - Verification of the pump with administration sets and compatible syringes
  - Verification of the Space Station functionality for stacking and using multiple pumps
- Electrical Safety per IEC 60601-1, EMC Testing per IEC 60601-1-2, and Essential Performance testing per IEC60601-2-24: 2012 was successfully conducted
  - Essential Performance was defined as follows:
    - Infusion of liquids without variation of infusion rate
    - Pressure limitation as protection from the bursting of the infusion line
    - Protection against unintended bolus volumes and occlusion (added by IEC 60601-2-24)
    - Alarm signal of high priority (added by IEC 60601-2-24).
- Electromagnetic Compatibility and Wireless testing was evaluated per the following: IEC 60601-1-2, FDA Guidance Document “Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices”, FDA Guidance Document “Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff”
- Li-ion and NiMH battery safety successfully tested per IEC 62133
- Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
- 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.

Clinical Tests

No clinical testing was performed as the Perfusor® Space Syringe Pump System does not require clinical studies to demonstrate substantial equivalence with the predicate device.

Conclusions

Results of functional and performance testing conducted on the subject device demonstrate that the Perfusor® Space Syringe Infusion Pump System is substantially equivalent to the predicate devices cleared under K092313 and K06299.