K062700

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5. 510(k) Summary

OCT 26 2006

APPLICANT:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Scott Pease
Manager, Regulatory Affairs
Phone: 610-596-2376

K-57

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FDA/CDRH/OIVD/PMO

RECEIVED

SUBMITTER:

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
GERMANY

Contact: Thomas Möller
Manager, Regulatory Affairs
Phone: 49 5661 71-1349

DEVICE NAME: Infusomat® Space Volumetric Infusion Pump System

COMMON OR USUAL NAME: Infusion Pump and Intravascular Administration Sets

DEVICE CLASSIFICATION: Class II per Code of Federal Regulation Title 21 §880.5725: Infusion Pump, product code FRN and Enteral Infusion Pump, product code LZH; 21 CFR §880.5440: Intravascular Administration Set, product code FPA and Blood Transfusion Set, product code BRZ. Classification Panel: General Hospital.

PREDICATE DEVICES: Predicate device for infusion pump: B. Braun Medical Inc. Vista Basic with *fm* System 510(k) K023189; ALARIS Medical Systems, Alaris Medley™ Patient Care System 510(k) K030459, ALARIS Medical Systems, Alaris MEDLEY™ Pump Module 510(k) K950419.
Predicate device for administration sets: B. Braun Medical Inc. Millennium CRT Infusion Pump and Millennium CRT Infusion Pump Administration Sets 510(k) K972678.

DESCRIPTION: The Infusomat® Space Volumetric Infusion Pump System includes an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories.

HO II

Infusomat® Space Pump

The Infusomat® Space is a 12V DC or battery powered external, transportable, volumetric infusion pump. The Infusomat® Space utilizes a linear peristaltic pumping mechanism and is intended to provide infusions of parenteral and enteral fluids. The Infusomat® Space is intended for but not limited to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments. 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 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.

SpaceStation

The B. Braun Space Station is a 12V DC or battery powered flexible docking and communication system for the medical workplace, in particular the intensive medical care. It serves the perspicuous accommodation of the infusion and infusion-syringe pumps Infusomat® Space and Perfusor® Space. The pillar and mounting system synchronized system components enables the individualized workplace design.
The SpaceStation module allows the set-up of a complete pump system with up to 24 pumps. Up to four pumps can be installed in every SpaceStation. The pumps are supplied with power via the integrated power supply and the built-in connectors. Up to six SpaceStations can be set-up as a column with a total of 24 pumps. SpaceStation placed next to each other can be connected via special connection cables, if the maximum number of 24 pumps in maximum three columns is not exceeded.

SpaceCover

SpaceCover Standard or SpaceCover Comfort forms the top of each column. Every SpaceStation or a column of SpaceStations must be closed with a cover. Alarms are

signalled by a row of LEDs and a loudspeaker in the SpaceCover Comfort.
The SpaceCover Standard does not contain any additional electronics. It protects the upper connectors from humidity and damage and allows a single SpaceStation to be used as a carrying unit. The SpaceCover standard housing mainly consists of the bottom part and the upper part.
The design of the SpaceCover comfort corresponds to that of the SpaceCover standard. SpaceCover Comfort offers a greater system functionality and operating facility. The cover is equipped on its front side with a large and very well readable status and alarm display. All status and alarm conditions of the pumps within the system as well as of the pumps themselves are displayed.

DrugListEditor

The DrugListEditor Space is a programm to create a drug pool with drug names including the corresponding parameter. The DLE-Space only may be used together with the infusion pumps Infusomat® Space and Perfusor® Space. A download of a drug list into the respective pump is possible by using the HiBaSeD service tool.
The DrugListEditor is able to hold up to 3500 drug names with corresponding parameters. From this pool, single drug libraries can be compiled and stored. The drug pool is saved as a binary file on the computer.

Administration sets

The administration sets are single-use, sterile, non-pyrogenic, disposable devices for use with the B. Braun Infusomat® Space Volumetric Infusion Pump for pump and gravity administration of fluids. There are currently 13 administration set configurations available including basic sets, burette sets, additive sets, filtered sets, epidural sets, low adsorption sets, add-on sets and blood sets.
The Infusomat® Space Volumetric Infusion Pump administration sets will be available in lengths ranging from 88 in. (224 cm) to 136 in. (345 cm), drops/mL ranging from 10 to 60 and priming volumes ranging from approximately 13 to 39 mL. All sets are latex free and all but one of the sets is DEHP-Free. The only DEHP containing item is the tubing portion of the blood filter component of the blood administration set. All other tubing components are DEHP free. The epidural

administration set has a yellow stripe in the tubing. All other tubing segments are clear.

Each set contains a segment of tubing intended to interface with the linear peristaltic mechanism of the pump. This segment of tubing is composed of silicone. There are two connectors at each end of the pump tube segment to ensure proper placement of the set into the pump. The silicone tubing provides greater resistance to loss of shape from the peristaltic pumping action compared to standard PVC tubing.

Each set also contains a free flow protection clamp. This clamp is intended to prevent free flow of fluid when the pump door is opened and the set is removed. The free flow protection clamp is specifically designed to interface with a mating receptacle in the pump. The free flow protection clamp is forced in to the open position when the pump door is closed; however, fluid flow does not begin until the run button is pressed. When the pump door is opened, the free flow protection clamp is forced into the closed position; thus stopping fluid flow and protecting against free flow.

INTENDED USE:

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, 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 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.

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SUBSTANTIAL EQUIVALENCE:

The Infusomat® Space Volumetric Infusion Pump System, including an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories has the same intended use, operation, and function as the Vista Basic with *fm* System distributed by B. Braun Medical Inc., 510(k) K023189, Alaris Medley™ Patient Care System distributed by ALARIS Medical Systems, 510(k) K030459, and Millennium CRT Infusion Pump and Millennium CRT Infusion Pump Administration Sets (now referred to as the Vista Infusion Pump and Adminsitration Sets) distributed by B. Braun Medical Inc., 510(k) K972678. There are no differences between the subject device and the predicate devices that raise new issues of safety and effectiveness.

The subject and the predicate devices are software controlled, electronic, external, volumetric infusion pumps, composed of injection molded thermoplastic components. The components of the subject and predicate devices are non solution contact. The subject and predicate devices are similar in operation, as they are all linear peristaltic volumetric infusion pumps. The subject and predicate devices achieve fluid delivery in a similar manner by the cyclical crushing action of the pumping fingers of the peristaltic mechanism on a straight piece of tubing. The subject and predicate devices are also similar in that they are used in the hospital or home health care setting to control the infusion rate of parenteral fluids to the patient.

The included accessories of the Infusomat® Space Volumetric Infusion Pump System are similar to the predicate devices in that they all offer the clinician maximum flexibility in providing infusion therapy. The subject and predicate systems provide possibilities to clean up and organize the patient bedside by storage different pumps in a filing and communication system. This filing and communication system provides central power supply to the single pumps and tubing retainers to prevent IV line confusion. Also the subject and the predicate provide a means for easy transportation of the modules as well as of the system. Additionally the subject and predicate devices are used to customize the menu items and drug library parameters for each facility. The calibration preventive

maintenance of the pump can also be stored in each device and the users notified when such calibration or routine maintenance is due to be completed.

The subject administration sets and the predicate administration sets are similar in that they are both single-use, sterile, non-pyrogenic, disposable devices for use with an external linear peristaltic volumetric infusion pump. Both the predicate and subject administration sets contain a free flow protection clamp intended to prevent free flow when the door is opened and the set is removed. The predicate device contains a straight piece of tubing to interface with the pump. Whereas the subject device contains a dedicated piece of silicone tubing to interface with the pump. Both the predicate and subject devices contain standard administration set components (spike, injections sites, roller clamps, slide clamps, check valves, filters, luers, etc.). Both the subject and predicate administration sets are intended for use with a specific infusion pump controlled volumetric infusion of parenteral and enteral fluids. The subject and predicate administration sets are also intended for use independent of their respective pumps for gravity controlled infusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

B. Braun Medical, Incorporated
C/O Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Incorporated
1775 Old Hwy 8 NW
New Brighton, Minnesota 55112-1891

Re: K062700
Trade/Device Name: Infusomat® Space Volumetric Infusion Pump System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 4, 2006
Received: October 11, 2006

Dear Mr. Preiss:

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.

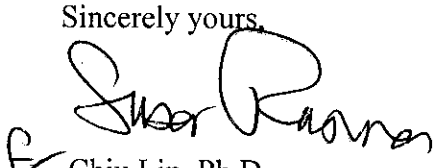
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K062744

Device Name: Infusomat® Space Volumetric Infusion Pump System

Indications For Use:

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).

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number: K062744