K062699

5. 510(k) Summary

APPLICANT:

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

OCT 26 2006

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

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: Perfusor® Space Infusion Syringe Pump System

COMMON OR USUAL NAME: Infusion Syringe Pump

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. Classification Panel: General Hospital.

PREDICATE Predicate device for infusion syringe pump: B. Braun Medical Inc. Perfusor® compact with fm-System, marketed under cleared 510(k) K022575 and MEDLEY™ System with Medication Management System, marketed by ALARIS Medical Systems Inc. under cleared 510(k) K030459 together with MEDLEY™ Syringe Pump Module marketed by ALARIS Medical Systems Inc. under cleared 510(k) K023264

K-61

DESCRIPTION:

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

Perfusor® Space

The Perfusor® Space is a 12V DC or battery powered external, transportable, infusion syringe pump. The Perfusor® Space utilizes a swivel-drive pumping mechanism is intended to provide infusions of parenteral and enteral fluids. The Perfusor® 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 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.
The Perfusor® Space uses standard, single-use, disposable syringes (with luer-lock connectors) designed for use on syringe pumps and validated on the Perfusor® Space. For a list of compatible, FDA cleared syringes please refer to the instructions for use of the Perfusor® Space.

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.

INTENDED USE:

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).

SUBSTANTIAL EQUIVALENCE:

The Perfusor® Space Infusion Syringe Pump System, including an external transportable electronic volumetric infusion pump and pump accessories has the same intended use, operation, and function as the Perfusor® compact with fm-System, marketed under cleared 510(k) K022575 and MEDLEY™ System with Medication Management System, marketed by ALARIS Medical Systems Inc. under cleared 510(k) K030459 together with MEDLEY™ Syringe Pump Module marketed by ALARIS Medical Systems Inc. under cleared 510(k) K023264.
The subject and the predicates are all computer controlled electrical, external, swivel-driven infusion syringe pumps composed of injection molded thermoplastic components. The components of the subject and predicate pumps are all non solution contact parts. The subject and predicates are also similar in that they are used in the hospital or home health care setting to control the infusion rate of parenteral and enteral fluids to the patient. The subject and predicates achieve fluid delivery in a similar manner while using standard, single-use, disposable syringes (with luer-lock connectors) designed for use on syringe pumps and validated with the pumps.

The included accessories of the Perfusor® Space Infusion Syringe 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

K062699
(P.5 of 5)

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 26 2006

Re: K062699
Trade/Device Name: Perfusor Space Infusion Syringe 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.

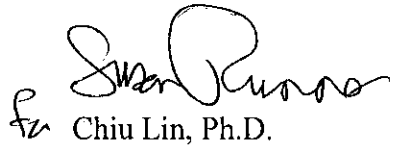
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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): K062699

Device Name: Perfusor® Space Infusion Syringe Pump System

Indications For Use:

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).

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)

(Div Off)
Anesthesiology, General Hospital,
Control, Dental Devices

Number: K062699