5. 510(k) Summary

SUBMITTER:

B Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212, Melsungen
Germany

JAN 29 2008

CONTACT:

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B. Braun Medical Inc.
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DEVICE NAME: Solcart B

COMMON OR USUAL NAME: Sodium Bicarbonate for Hemodialysis

DEVICE CLASSIFICATION: Hemodialysis system and accessories
Class II, CFR Title 21 § 876.5820

PREDICATE DEVICE: Gambro BiCart® (K013724)

DESCRIPTION: Solcart B consists of a powder concentrate used to prepare bicarbonate concentrate solution for use in hemodialysis. Solcart B is a non-refillable polypropylene cartridge containing dry sodium bicarbonate [in compliance with European Pharmacopoeia (Ph. Eur.) and United States Pharmacopoeia (USP)] for hemodialysis. It must be used together with a suitable acid concentrate and water meeting the requirements of the Association for the Advancement of Medical Instrumentation (AAMI).

Solcart B must only be used with B. Braun dialysis machines provided with a holder for powder bicarbonate cartridges.

INTENDED USE: Solcart B is intended for use in bicarbonate hemodialysis for acute and chronic renal failure, or acute intoxication with dialyzable substances.

SUBSTANTIAL EQUIVALENCE:

The Solcart B cartridges have the same intended use and technological characteristics as the stated predicate device, the Gambro BiCart® cartridges (K013724). There are no differences between the predicate and the proposed device that raise new issues of safety and effectiveness. The proposed device has been subjected to biocompatibility testing, functional performance testing and stability testing to support safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2008

B. Braun Medizintechnologie GmbH
c/o Ms. Tracy Maddock
Senior Regulatory Affairs Analyst
B. Braun Medical, Inc.
901 Marcon Blvd.
ALLENTOWN PA 18109

Re: K072760
Trade/Device Name: Solcart B
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: January 17, 2008
Received: January 22, 2008

Dear Ms. 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K072760

Device Name: Solcart B

Indications For Use:

Solcart B is intended for use in bicarbonate hemodialysis for acute and chronic renal failure, or acute intoxication with dialyzable substances.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072760