5. 510(k) SUMMARY

APR 2 5 2011

DATE: July 30, 2010

APPLICANT:
B. Braun Avitum AG
Schwarzenberg Weg 73-79
34212 Melsungen Germany
Establishment Registration Number: 3002879653

SUBMITTER:
B. Braun Medical Inc.
901 Marcon Blvd.
Allentown, PA 18109-9341
Telephone: (610) 266-0500

CONTACT:
Angela Caravella
Senior Regulatory Affairs Analyst
Telephone: (610) 596-2966
Facsimle: (610) 596-4962
E-Mail: angela.caravella@bbraun.com

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
Product Code: KPO

CURRENTLY MARKETED DEVICE (PREDICATE): Solcart B (K072760)

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).

The Solcart B cartridge is designed to fit into cartridge holder adapters affixed to the hemodialysis machine. The 1100g cartridge may only be used with B. Braun hemodialysis machines for which the use of powder bicarbonate cartridges is a stated option and the machine is equipped with a holder for the bicarbonate cartridge.

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 cartridge, containing 1100g sodium bicarbonate concentrate powder, has the same intended use and utilizes the same fundamental technology as the predicate device, the currently marketed Solcart B sodium bicarbonate concentrate powder in cartridges labeled to contain 650g and 760g and cleared for market in 510(k) K072760. The proposed Solcart B in the 1100g cartridge can be considered a line extension to the Solcart B 650g and 760g sodium bicarbonate cartridges.

The technological characteristics of the 1100g cartridge for the proposed Solcart B dialysis concentrate powder are equivalent to those of the existing 650g and 760g sodium bicarbonate cartridges. The Solcart B 1100g cartridge is the same as the predicate device in material composition and components. However, the proposed device has a larger body and a larger cartridge cap to accommodate the additional amount of Solcart B dialysis concentrate powder.

Because the powder concentrate has not changed in formulation, the proposed addition of 1100g sodium bicarbonate cartridge size does not pose a significant impact upon the fundamental technology of Solcart B, as identified within the Design Control Activities Summary.

NONCLINICAL TESTING:

The proposed device was subjected to package and ship tests to demonstrate the acceptability of the packing and shipping configuration. In addition, performance testing was conducted with the proposed Solcart B 1100g cartridge to demonstrate compatibility with B. Braun hemodialysis machines. The stability testing conducted on the Solcart B 1100g cartridge verifies that the product meets the defined specifications.

CONCLUSION:

Verification and validation testing for the proposed Solcart B 1100g cartridge device are complete and all acceptance criteria have been met. The testing demonstrates that there are no differences between the predicate and the proposed devices that raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

B. Braun Avitum AG
c/o Ms. Angela Caravella
Senior Regulatory Affairs Analyst
B. Braun Medical, Inc.
901 Marcon Blvd.
ALLENTOWN PA 18109-9341

APR 2 5 2011

Re: K102194
Trade/Device Name: Solcart B Sodium Bicarbonate Powder Dialysis Concentrate, 1100g Cartridge
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: April 12, 2011
Received: April 15, 2011

Dear Ms. Caravella:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102194

Device Name: Solcart B Sodium Bicarbonate Powder Dialysis Concentrate, 1100g Cartridge

Indications For Use:

Solcart B Powder Dialysis Concentrate 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102194