5. 510(k) SUMMARY

APR 22 2010

APPLICANT:	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen, Germany Establishment Registration Number: 3002879653
SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 610-266-0500
CONTACT:	Angela J. Caravella Sr. Regulatory Affairs Analyst Phone: 610-596-2966 Fax: 610-596-2502 E-mail: Angela.Caravella@bbraun.com
DEVICE NAME:	Diacap® Polysulfone HiFlo 23 Hemodialyzer
COMMON OR USUAL NAME:	High Permeability Hemodialysis System
DEVICE CLASSIFICATION:	Class II per 21 CFR § 876.5860 Product Code KDI
CURRENTLY MARKETED DEVICE (PREDICATE):	Diacap® LO PS (10, 12, 15) and Diacap® HI PS (10, 12, 15, 18, 20) Hemodialyzers, (K071518)
DESCRIPTION:	The Diacap® Polysulfone HiFlo 23 Hemodialyzer is a high permeability dialyzer intended to be used in acute and chronic hemodialysis. It is composed of polysulfone hollow fiber capillary membranes in a polycarbonate housing with a polyurethane potting resin and a silicone O-ring. The proposed Diacap HiFlo 23 hemodialyzer will be available in one model, the 23, which represents the effective surface area of 2.3m^2. The dialyzer is intended for single use and is provided sterile.
INTENDED USE:	The Diacap® Polysulfone HiFlo 23 Hemodialyzer is designed for single use in acute and chronic hemodialysis.

SUBSTANTIAL EQUIVALENCE:

Diacap® Polysulfone HiFlo 23 Hemodialyzer has the same intended use and utilizes the same fundamental technology as the predicate device, the currently marketed Diacap LO PS (10, 12, 15) and Diacap HI PS (10, 12, 15, 18, 20) Hemodialyzers, (K071518). The Diacap HiFlo 23 Hemodialyzer is a modified version of the existing Diacap LO PS and HI PS dialyzers and can be considered an extension to the line of B. Braun Polysulfone Dialyzers.

The technological characteristics of the Diacap Polysulfone HiFlo 23 Hemodialyzer are equivalent to those of the existing Diacap polysulfone dialyzers. The Diacap Polysulfone HiFlo 23 Hemodialyzer is similar to the predicate device in material composition. Changes in the design of the proposed dialyzer include an increased surface area and two alternate materials have been added: polyurethane (PUR) potting resin and an alternate silicone material qualified for the dialyzer O-ring.

These changes do not pose a significant impact upon the fundamental technology of the Diacap polysulfone capillary dialyzers, as identified within the Risk Analysis. Verification and validation testing for the proposed dialyzer have been completed and all acceptance criteria have been met. The testing demonstrated that there are no differences between the predicate and the proposed device that raise 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

JUN - 3 2010

B.Braun Avitum AG
% Ms. Angela J. Caravella
Sr. Regulatory Affairs Analyst
B. Braun Medical, Inc.
901 Marcon Boulevard
ALLENTOWN PA 18109-9341

Re: K100334
Diacap® Polysulfone HiFlo 23 Hemodialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: March 30, 2010
Received: April 1, 2010

Dear Ms. Caravella:

This letter corrects our substantially equivalent letter of April 22, 2010. 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 (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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K100334

Device Name: Diacap® Polysulfone HiFlo 23 Hemodialyzer

Indications For Use:

The Diacap® Polysulfone HiFlo 23 Hemodialyzer is designed for single use in acute and chronic hemodialysis.

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, Abdominal,
and Radiological Devices
510(k) Number K100334