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510(k) SUMMARY
in accordance with 21 CFR 807.92(c)

AUG 17 2007

1. Owner:

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

Contact:

Ms. Susan Olinger
Corporate Vice President, Regulatory Affairs
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
Telephone: (610) 596-2517
Fax: (610) 266 4962
Email: susan.olinger@bbraun.com

Date of Preparation: May 31, 2007

2. Device Classification:

		Conventional	High Permeability
1.	Common or Usual Name	Polysulfone Hemodialyzer	Polysulfone Hemodialyzer
2.	Trade Name	Diacap LO PS 10 Diacap LO PS 12 Diacap LO PS 15	Diacap HI PS 10 Diacap HI PS 12 Diacap HI PS 15 Diacap HI PS 18 Diacap HI PS 20
3.	Classification Name	Hemodialysis system and accessories	High permeability hemodialysis system
4.	Regulation Number	21 CFR §876.5820	21 CFR §876.5860
5.	Class	II	II
6.	Classification Product Code	FJI	KDI
7.	Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
8.	Prescription Status	Prescription device as described in 21 CFR §801.109	Prescription device as described in 21 CFR §801.109

3. Predicate Device

Diacap Models		Fresenius Models 510(k) number K970700	
Trade Name	**Surface Area m^2**	**Trade Name**	**Surface Area m^2**
Low Flux Models (Conventional)			
LO PS 10	1.0 m^2	Hemoflow F5	1.0 m^2
LO PS 12	1.2 m^2	Hemoflow F6	1.3 m^2
LO PS 15	1.5 m^2	Hemoflow F7 Hemoflow F8	1.6 m^2 1.8 m^2
High Flux Models			
HI PS 10	1.0 m^2	Hemoflow F 50 NR	1.0 m^2
HI PS 12	1.2 m^2	Hemoflow F 60 A Hemoflow F 60 B	1.3 m^2
HI PS 15	1.5 m^2	Hemoflow F 70 A Hemoflow F 70 B Hemoflow F 70 NR	1.6 m^2
HI PS 18	1.8 m^2	Hemoflow F 80 A Hemoflow F 80 B	1.8 m^2
HI PS 20	2.0 m^2	Optiflux 200 A	2.0 m^2

4. Device Description:

The Diacap LO PS (10, 12 and 15) and Diacap HI PS (10, 12, 15, 18 and 20) are, respectively, conventional permeability and high permeability hemodialyzers. The hollow, polysulfone membrane is housed within a plastic cylinder with four ports: two ports for blood compartment access and two ports for dialysate access.

5. Intended Use:

The Diacap LO PS (10, 12 and 15) and Diacap HI PS (10, 12, 15, 18 and 20) hemodialyzers are designed for single use in acute and chronic hemodialysis.

6. Substantial Equivalence Comparison:

Technical and clinical comparisons presented in the premarket notification submission are based upon the information requested in the August 7, 1998 *Guidance for Industry and CDRH Reviewers, Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers*, section V. The evaluation of device materials and configuration, membrane characteristics, blood volumes, sterilization methods and the results of randomized clinical studies demonstrate that the Diacap LO PS and Diacap HI PS do not raise any new issues of safety and effectiveness when compared with the predicate device.

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7. Performance Evaluations:

Performance and safety evaluations of Diacap LO PS (10, 12 and 15) and Diacap HI PS (10, 12, 15, 18 and 20) were based upon bench and clinical testing. Ultrafiltration coefficients and clearances of urea, creatinine, phosphate and vitamin B_{12} were consistent with expected values for conventional and high permeability dialyzers. Hemocompatibility was confirmed by white cell and platelet counts and the evaluation of complement activation (C3a), intrinsic and extrinsic coagulation system (TAT and thrombocyte activation) and cell activation (thrombocyte and/or leukocyte adhesion and leukocyte activation).

8. Conclusion:

The performance and safety data presented in the premarket notification support a finding of substantial equivalence between the Diacap LO PS (10, 12 and 15) and HI PS (10, 12, 15, 18 and 20) and the predicate devices already in commercial distribution in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 17 2007

B. Braun Medizintechnologie G.m.b.H.
c/o Ms. Susan Olinger
Corporate Vice President, Regulatory Affairs
B. Braun Medical, Inc. (U.S.)
901 Marcon Blvd.
ALLENTOWN PA 18109

Re: K071518
Trade/Device Name: Diacap LO PS (10, 12, 15) and Diacap HI PS (10, 12, 15 18, 20) Hemodialyzers
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Product Code: KDI
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Product Code: FJI
Regulatory Class: II
Dated: May 31, 2007
Received: June 4, 2007

Dear Ms. Olinger:

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 (Premarket Approval), 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 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" (21 CFR 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,

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

Indications for Use

510(k) Number (if known): K071518

Device Name: Diacap LO PS (10,12,15) and Diacap HI PS (10,12,15,18,20) Hemodialyzers

Indications for Use: Diacap LO PS (10, 12, 15) and Diacap HI PS (10, 12, 15, 18, 20) Hemodialyzers are designed for single use in acute and chronic hemodialysis.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(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 K071518