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AUG 27 2004

510(K) SUMMARY

Submitter's Name:	David E. Curtin, RAC
Address:	1620 Waukegan Rd. MPGR-A2E
Phone:	(847) 473-6079
Fax:	(847) 473-6952
Contact:	David E. Curtin
Date Prepared:	5/26/04
Trade Name:	Accusol Dialysis Solution
Common Name:	Dialysis Solution
Classification Name:	Dialysate Concentrate for Hemodialysis (Liquid or Powder) per 21 CFR 876.5820 Hemodialysis System and Accessories. The Product/Classification code is KPO.
Equivalent Predicate:	PrismaSate Dialysis Solutions, K013448 Gambro Renal Products Premixed Dialysate for Hemodiafiltration, K910270 Baxter Healthcare Corporation BIASOL Liquid Concentrate, K895199 Baxter Healthcare Corporation
Device Description:	Accusol Dialysis Solution is a bicarbonate based solution used in continuous renal replacement therapies
Intended Use:	Accusol Solutions are indicated for use as dialysis solutions in Continuous Renal Replacement Therapy

Summary of the Technological Characteristics Compared to the Predicate Device:	Accusol Dialysis Solution is formulated of the same solution components to the same quantitative levels as dialysis solutions used to formulate the PrismaSate and BIASOL products. The Accusol Dialysis Solution container system is similar in design to the PrismaSate Dialysis Solution container system and to the materials of construction and closure system of the Premixed Dialysate for Hemodiafiltration products.
Additional Information Requested by FDA:	None to date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

David E. Curtin, RAC
Associate Director, Regulatory Affairs
Baxter Healthcare Corporation
Renal Division
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K041428
Trade/Device Name: Accusol Dialysis Solution
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: August 19, 2004
Received: August 20, 2004

Dear Mr. Curtin:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

510(K) Number (if known): K041428

Device Name: Accusol Dialysis Solution

Indications for Use:

Accusol Solutions are indicated for use as dialysis solutions in Continuous Renal Replacement Therapy.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109

(Optional Format 1/2/96)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041428