K041683 Page 1 of 1

AUG 27 2004

8.0 510(k) Summary

SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 (610) 266-0500, ext. 2516 Contact: Jennifer A. Pung, Senior Analyst, Regulatory Affairs
DEVICE NAME:	B. Braun Bicarbonate Dialysate
COMMON OR USUAL NAME:	Bicarbonate Dialysate
DEVICE CLASSIFICATION:	Class II, 21 CFR § 876.5820, Hemodialysis System and Accessories (Product Code KPO)
PREDICATE DEVICE:	Gambro Renal Products – Gambro PrismaSate Dialysis Solutions for Continuous Renal Replacement Therapy (K013448)
DESCRIPTION:	The B. Braun Bicarbonate Dialysate Solutions are a family of sterile, non-pyrogenic, bicarbonate dialysate solutions. The solutions will be provided in flexible two-chamber bags, with bicarbonate solution in one chamber and electrolyte solution in the other chamber. The chambers are separated by a peel seam. The 5,000 mL ready-to-use solution is obtained by pressing on the small chamber of the bag until the peel seam opens, and then rocking the bag back and forth to mix the contents.
INTENDED USE:	B. Braun Bicarbonate Dialysate is indicated for use with renal replacement therapy systems that utilize sterile bicarbonate dialysate.
SUBSTANTIAL EQUIVALENCE:	The B. Braun Bicarbonate Dialysate has a similar composition range, container/closure system, and indications for use as the PrismaSate Dialysis Solutions marketed by Gambro under the 510(k) Premarket Notification K013448.

C000031

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Ms. Jennifer A. Pung
Senior Analyst, Regulatory Affairs
B. Braun Medical, Inc.
901 Marcon Blvd.
ALLENTOWN PA 18109-9341

Re: K041683
Trade/Device Name: B. Braun Bicarbonate Dialysate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: June 18, 2004
Received: June 21, 2004

Dear Ms. Pung:

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.

2.0 Indications for Use Statement

510(k) Number (if known): K041683

Device Name: B. Braun Bicarbonate Dialysate

Indications For Use:

B. Braun Bicarbonate Dialysate is indicated for use with renal replacement therapy systems that utilize sterile bicarbonate dialysate.

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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041683