GAMBRO Renal Products

510(k) Premarket Notification

510(k) Summary

K013724

JAN 8 2002

BiCart®

Sodium Bicarbonate for Hemodialysis

Contact Information:

GAMBRO Renal Products
1845 Mason Avenue
Daytona Beach, FL 32117
Phone: 386-274-2811
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Contact: Fei Law

Prepared: November 5, 2001

510(k) Summary

Name of the device: Gambro BiCart®

Common Name: Sodium Bicarbonate for Hemodialysis

Classification Name: Dialysate Concentrate for Hemodialysis (Liquid or Powder) per 21 CFR 876.5820. The Product/Classification Code is KPO.

Predicate Devices:

Gambro BiCart® System
K873155 cleared 10/26/1987
Gambro, Inc.
Manufactured by Gambro Lundia AB

Gambro BiCart® 720g
K940601 cleared 03/22/1994
C.G.H Medical, Inc.
Manufactured by Gambro Lundia AB

Device Description:

Gambro BiCart® Sodium Bicarbonate for hemodialysis is a dry concentrate used to prepare bicarbonate concentrate solution for use in conventional hemodialysis.

The Gambro BiCart® is a non-refillable cartridge containing sodium bicarbonate, which enables on-line preparation of bicarbonate hemodialysis solution. It is used in conjunction with appropriate acid dialysis concentrate and water meeting Association for the Advancement of Medical Instrumentation (AAMI) guidelines. The resulting dialysate is used in conventional, commercially available hemodialysis machines/monitors which have been adapted to receive the cartridges.

Indications for Use:

Gambro BiCart® is indicated for use in a bicarbonate hemodialysis for acute and chronic renal failure, or acute intoxication with dialyzable substances.

510(k) Summary

Comparison to Predicate Devices:

The Gambro BiCart® Sodium Bicarbonate for Hemodialysis cartridges are equivalent to the Gambro BiCart® System (includes 650g BiCart®) and the Gambro BiCart® 720g which have been previously approved by the FDA under Premarket Notifications K873155 and K940601. This Premarket Notification is intended to add cartridge sizes to existing product offerings. The only functional difference between the different sizes is the quantity of sodium bicarbonate contained in the cartridge. The varying quantities of sodium bicarbonate provide for varying lengths of treatment. The resulting bicarbonate concentrations for all cartridge sizes are identical, and the resulting solution is used in exactly the same way.

	Gambro BiCart® System K873155 cleared 10/26/1987	Gambro BiCart® 720g K940601 cleared 03/22/1994	Gambro BiCart® (various sizes, including 650, 720, and 1150g)
Manufacturer	Gambro Lundia AB	Gambro Lundia AB	Gambro Lundia AB
Indication for Use	Bicarbonate hemodialysis for acute and chronic treatment of renal failure	Bicarbonate hemodialysis for acute and chronic treatment of renal failure	To be used in bicarbonate hemodialysis treatment for patients suffering from acute renal failure, chronic renal failure, or acute intoxication with dialyzable substances
Indication included in labeling	In cases of poisoning by substances which can be removed by hemodialysis	In cases of poisoning by substances which can be removed by hemodialysis	
Disposable?	Yes	Yes	Yes
Sodium Bicarbonate Grade	USP & European Pharmacopoeia	USP & European Pharmacopoeia	USP & European Pharmacopoeia
Sodium Bicarbonate Weight Spec.	Target (± 50g)	Target (± 50g)	Target (+ 30g)
Bicarbonate Concentration	38 mEq/L	38 mEq/L	38 mEq/L
Storage Conditions	Store below +40 °C (+104 °F)	Store below +40 °C (+104 °F)	Store below +40 °C (+104 °F)
Housing Material	Polypropylene	Polypropylene	Polypropylene

Comparing the proposed device to the predicate devices, its indication for use, technological characteristics, and chemical composition are identical. We therefore consider this device to be substantially equivalent to existing products in commercial distribution in the United States.

Performance Data

No clinical testing was performed.
No testing was necessary to determine equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Ms. Fei Law
Quality Assurance Manager
Gambro Renal Products
1845 Mason Avenue
DAYTONA BEACH FL 32117

Re: K013724
Trade/Device Name: Gambro BiCart®
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: November 5, 2001
Received: November 9, 2001

Dear Ms. Law:

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 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:

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" (21 CFR Part 807.97). 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): K013724

Device Name: Gambro BiCart®

Indications For Use:

Gambro BiCart® is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure, or acute intoxication with dialyzable substances.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013[redacted]

(Optional Format 3-10-98)

Prescription Use ✓