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K030366

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5 510(k) Summary

Submitter Information:

Company Name:	Dialysis Systems, Inc.
Company Address:	2000 Blair Boulevard Nashville, TN 37212
Company Phone	615-292-0333
Company Fax:	615-292-7375
Contact Person(s):	1. Mark Vesligaj 2. Michael Peterson
Prepared:	January 17, 2003
Trade Name:	Bicarbonate Mixing System
Classification Name:	Hemodialysis System and Accessories (21 CFR 876.5820)
Substantial Equivalence:	G.E.M. Water Systems, International Sodium Bicarbonate Mixers/Delivery Systems 510(k)# K970674
Intended Use:	This device is intended for the mixing of sodium bicarbonate powder with water for hemodialysis treatment.
Device Description:	Dialysis Systems Inc.'s Bicarbonate Mixing System provides for batch mixing of bicarbonate liquid concentrate and transfer to a loop tank. The mixing tank works in conjunction with an external closed-loop mixing circuit that includes a pump and an eductor. The pump circulates liquid from the mixing tank, through the eductor and back into the mixing tank. The eductor is connected to a sodium bicarbonate additive hopper. A measured amount sodium bicarbonate additive is drawn into the mixing tank by the flow of fluid through the eductor. Mixing of the powder to create a bicarbonate liquid concentrate is accomplished by the mixing action of the eductor, the return flow to the mix tank and by further mixing action created by nozzles as the fluid is re-circulated back into the mix tank.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2004

Mr. Mark Vesligaj Jagotrab
Vice President
Dialysis Systems, Inc.
2003 Blair Boulevard
NASHVILLE TN 37212

Re: K030366
Trade/Device Name: DSI BiCarb Mixing System
Regulation Number: 21 CFR 876.§5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FIN
Dated: March 29, 2004
Received: April 1, 2004

Dear Mr. Vesligaj Jagotrab:

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

Indications for Use

510(k) Number (if known): K030366

Device Name: Bicarbonate Mixing System

Indications for Use:

The intended use of the Dialysis Systems Inc. Bicarbonate Mixing System is the mixing of water and sodium bicarbonate powder for hemodialysis treatment and the delivery of the mixture to the treatment floor.

Prescription Use ___√___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagmm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030366