JUN 2 8 2004

510(k) Summary

Date: 9/26/03

Submitter:

Jack Dillon
Medical Solutions International, Inc
11522 West 90th St.
Overland Park, KS 66214
Ph: 913-438-9700
Fx: 913-438-9701
medsolinc@sbcglobal.net

Contact Person:

Jarvis Stirn
938 Tennessee St.
Lawrence, KS 66044
Ph: 785-843-0144
wildhawk@hotmail.com

Device Identification:

Trade Name/Proprietary Name:
Device: BiPro Model SDS-CB200

Common Name: Mixing and distribution system of bicarbonate for dialysis.

Classification Name and Reference:

Classification Names:	TANK, HOLDING, DIALYSIS AND ACCESSORIES
Classification:	Class II, 21 CFR 876.5820 Panel: Gastroenterology Product Code: 78 FIN

Premarket Notification Number: No Prior Related Premarket Notification Submissions.

Indications for Use:
BiPro Model SDS-CB200 is intended for use in a hemodialysis facility for mixing and distribution of sodium bicarbonate (bicarb) to remote points of use. The bicarb is then mixed with purified water and acid to create the dialysate solution used in hemodialysis.

Device Description:
The Medical Solutions BiPro Models provide semi-automatic mixing of bicarb concentrates from storage to hemodialysis patient stations. A mix tank is used for the mixing of bicarb concentrates and RO water. After mixing the bicarb solution, it is transferred to a loop (day) tank, via the mix pump, where the bicarb solution is distributed to the dialysis machine.

Statement of Substantial Equivalence:
The Medical Solutions BiPro Model is substantially equivalent in intended use, features, functions, and technological characteristics to the Mar Cor Services, Inc Bicarb System (K003560)

Performance: Safety and Effectiveness Information:
Medical Solutions BiPro Systems have been voluntarily tested to meet the safety requirements ANSI/AAMI RD62: 2001 Water Treatment Equipment for Hemodialysis Applications. The ANSI/AAMI RD62: 2001 Water Treatment Equipment for Hemodialysis Applications is a revision of the ANSI/AAMI RD5: 1992 Hemodialysis Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2004

Mr. Jack Dillon
Medical Solutions International, Inc.
11522 West 90th Street
SHAWNEE MISSION KS 66215

Re: K033118
Trade/Device Name: BiPro Model SDS-CB200
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FIN
Dated: April 29, 2004
Received: April 29, 2004

Dear Mr. Dillon:

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): K033118

Device Name: BiPro Bicarb Mixing/Distribution System (BiPro SDS-CB200)

Indications For Use:

BiPro Model SDS-CB200 is intended for use in a hemodialysis facility for mixing and distribution of sodium bicarbonate (bicarb) to remote points of use. The bicarb is then mixed with purified water and acid to create the dialysate solution used in hemodialysis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033118