K022521

Section 13. 510(k) Summary

JAN 0 3 2003

510(k) SUMMARY

SUBMITTER: **Rockwell Medical Technologies, Inc.**
30142 Wixom Road
Wixom, MI 48393
Phone: 248-960-9009

DATE PREPARED: **July 24th, 2002**

DEVICE NAME: **Bicarbonate Dialysate Concentrate Mixer**

CLASSIFICATION NAMES: **Accessory to Hemodialysis – Hemodialysis Bath Concentrate Mixing Device**

PREDICATE DEVICE: **Rockwell Medical Technologies' Dri-Sate™Mixer**
&
Fresenius USA, Inc. Hemodialysis Concentration Dissolution Unit P/N 89-290-09

Device Description:

The Rockwell Medical Technologies' Bicarbonate Dialysate Concentrate Mixer is designed to mix the Rockwell Medical Technologies Dri-Sate Bicarbonate Concentrate Mixes with purified water to produce a bicarbonate concentrate solution for hemodialysis for use in 3-stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines / monitors.

Hemodialysis therapy removes blood wastes by diffusion through a dialyzer membrane into a dialysate solution flowing on the opposite side of the dialyzer membrane. Hemodialysis also involves using a differential transmembrane pressure to ultrafilter water from the blood usually resulting in a net patient weight loss during the treatment.

The Rockwell Medical Technologies' Bicarbonate Dialysate Concentrate Mixer is designed to be used with The Rockwell Medical Supply, LLC. Dri-Sate™ Bicarbonate Concentrate Hemodialysis Mixes which contain sodium bicarbonate and sodium chloride and in another formulation, only sodium bicarbonate (for Cobe Machines). These Dri-Sate™ Bicarbonate Concentrate Hemodialysis Mixes have been previously cleared by the FDA in 510(k) Number K954527 on March 1st, 1996. Copies of the 510(K) clearance letter and samples of the labels/instructions for use for these powders are included in Appendix II of this Notification. These are formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and acid concentrate in a three-stream hemodialysis machine.

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These powders when proportioned/ mixed with pre-treated or purified water meeting or exceeding AAMI Standards, may be used in conventional and commercially available hemodialysis machines or monitors as a hemodialysis solution. These proportioned hemodialysis solutions are heated to body temperature and then perfused through the dialysis fluid compartment of artificial kidneys or hemodialyzers. These bicarbonate hemodialysis solutions are separated from the patient's blood by means of a semi-permeable cellulosic or non-cellulosic membrane which serves as a molecular weight selective barrier to the passage of molecules beyond a certain molecular weight

Predicate Devices:

The Rockwell Medical Technologies, Inc. Bicarbonate Dialysate Concentrate Mixer is substantially equivalent to the Rockwell Medical Technologies Dri-Sate™ Mixer for Dri-Sate™ acid concentrate solutions and to the Fresenius USA, Inc. Hemodialysis Concentration Dissolution Unit P/N 89-290-09.
Examination of the information pertaining to the Rockwell Medical Technologies Bicarbonate Dialysate Concentrate Mixer demonstrates that this device is equivalent in composition, intended use, packaging and labeling to other mixing devices for hemodialysis concentrate solutions currently approved for commercial distribution in the United States by the FDA. There are no significant differences between these marketed products and our proposed device

Intended Use:

The Rockwell Medical Technologies' Bicarbonate Dialysate Concentrate Mixer is designed to mix the Rockwell Medical Technologies Concentrate Powders for Bicarbonate Dialysis with purified water to produce a bicarbonate concentrate solutions for hemodialysis for use in 3-stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines / monitors. The Rockwell Medical Technologies, Inc. Concentrate Powders for Bicarbonate Dialysis which are mixed with water in the Bicarbonate Dialysate Concentrate Mixer™ are indicated for use in acute and chronic hemodialysis

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, both devices utilize the same methods and technique for preparing hemodialysis concentrate solutions. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was not performed was not included in this 510(k) Notification.

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Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Rockwell Medical Technologies, Inc. Bicarbonate Dialysate Concentrate Mixer indicates that it is safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2003

Mr. Gerald A. Fritz
Director of Operations/Quality Assurance
Rockwell Medical Technologies
30142 Wixom Road
WIXOM MI 48393

Re: K022521
Trade/Device Name: Bicarbonate Dialysate Concentrate Mixer
Regulation Number: 21 CFR 876.§5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: October 28, 2002
Received: October 31, 2002

Dear Mr. Fritz:

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*):

DEVICE NAME: Rockwell Medical Technologies, Inc., Bicarbonate Dialysate Concentrate Mixer

INDICATIONS FOR USE:

Indications for Use Statement

The Rockwell Medical Technologies' Bicarbonate Dialysate Concentrate Mixer is designed to mix the Rockwell Medical Technologies Concentrate Powders for Bicarbonate Dialysis with purified water to produce a bicarbonate concentrate solutions for hemodialysis for use in 3-stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines / monitors. The Rockwell Medical Technologies, Inc. Concentrate Powders for Bicarbonate Dialysis which are mixed with water in the Bicarbonate Dialysate Concentrate Mixer™ are indicated for use in acute and chronic hemodialysis.

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

Concurrence of CDRH, Office of Device Evaluation (**ODE**)

Prescription Use N/ (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022521