510(K) SUMMARY

NOV 1 7 2006

SUBMITTER: Rockwell Medical Technologies, Inc.
30142 Wixom Road – Wixom, MI 18393 USA
Phone 248-960-9009 – fax 248-960-9119

DATE PREPARED: **July 19th, 2006**

DEVICE NAME: **CitraPure® Acid Concentrate**

CLASSIFICATION NAMES: **Concentrate Solutions for Hemodialysis**
Accessories to Hemodialysis

PREDICATE DEVICE: **Rockwell Medical Technologies Dri-Sate® Acid Concentrate**
Rockwell Medical Technologies Acidified Component Concentrates Containing Di-Acetate for Bicarbonate Dialysis
Advanced Renal Technologies DRYalysate Acid Concentrate
Advanced Renal Technologies Citrasate Dialysate Acid Concentrate Liquid

Device Description:

The Rockwell Medical Technologies, Inc. CitraPure® Acid Concentrate for Bicarbonate Dialysis powders and liquids contain salt, sugar, and non-sugar and powders formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and bicarbonate concentrate/powder. These solutions and 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. The hemodialysis concentrate solutions and powders presented in this 510K Notification are intended to be used in three stream hemodialysis machines in which an acidified concentrate is proportioned into one stream, a bicarbonate, chloride and sodium concentrate solution which has been prepared by mixing the powder with a specified volume of water and citric acid is proportioned into the second stream of the hemodialysis machine, and water is proportioned into the third stream. These three streams are then mixed to prepare a final proportioned hemodialysis solution.

Predicate Devices:

The Rockwell Medical Technologies, Inc. CitraPure® hemodialysis concentrate powders and liquids are substantially equivalent to the Rockwell Medical Technologies Dri-Sate® Acid Concentrate and the Advanced Renal Technologies DRYalsate concentrates for hemodialysis.

Intended Use:

The Rockwell Medical Technologies, Inc. CitraPure® Acid Concentrate powders/liquids for Bicarbonate Dialysate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/monitor and bicarbonate concentrate.

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 range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was performed to determine the chemical composition and range of composition. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed.

Conclusions:

Testing performed on the Rockwell Medical Technologies CitraPure® Acid Concentrate powders/liquids for bicarbonate dialysate 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Rob Chioini
President
Rockwell Medical Technologies
30142 Wixom Road
WIXOM MI 48393

NOV 17 2006

Re: K062399
Trade/Device Name: CitraPure® Acid Concentrate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: August 11, 2006
Received: August 21, 2006

Dear Mr. Chioini:

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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): __K062399_____

Device Name: Rockwell Medical Technologies CitraPure®

Indications for Use:

The Rockwell Medical Technologies CitraPure® Acid Concentrate powders/liquids for bicarbonate dialysate are indicated for use in acute and chronic hemodialysis and are to be used with the appropriate hemodialysis machine/monitor and bicarbonate concentrate.

Prescription Use ____√_____ ~~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)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062399