

Rockwell Medical Technologies Dri-Sate™ Mixer**Section 16. 510(k) Summary****510K(k) SUMMARY**

SUBMITTER: Rockwell Medical Technologies
28025 Oakland Oaks
Wixom, MI 48393
Phone: 248-546-0040

DATE PREPARED: October 14th, 1998

DEVICE NAME: Dri-Sate Mixer for Preparation of Acidified
Dialysate Concentrate

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

PREDICATE DEVICE: Fresenius USA, Inc. Hemodialysis Concentration
Dissolution Unit P/N 89-290-09

Device Description:

The Rockwell Medical Technologies' Dri-Sate™ Mixer is designed to mix the Rockwell Medical Technologies Dri-Sate Acid Concentrate Mixes with purified water to produce an acid 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' Dri-Sate™ Mixer is designed to be used with the Rockwell Medical Supply, LLC. Dri-Sate™ Acid Concentrate Hemodialysis Mixes which contain salt, sugar, and non-sugar and water containing solutions and powders. These are 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 Dri-Sate™ Acid hemodialysis Mixes which have been presented in a previously cleared 510K Notification (K981003) 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 glacial acetic acid is

Rockwell Medical Technologies Dri-Sate™ Mixer

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. These types of a final hemodialysis solutions are commonly referred to as "Bicarbonate Hemodialysis Solutions." These proportioned hemodialysis solutions are then 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. The molecular weight cut-off of each type of membrane may vary depending on the membrane type, manufacturing process, etc. The semi-permeable membrane in a hemodialyzer permits the passage of smaller molecular weight (less than 5,000 daltons for conventional cellulosic membranes), ionized and non-ionized molecules, waste products and toxins (i.e. blood urea nitrogen, creatinine, potassium, etc.) contained in the patient's blood circulating through the dialyzer, to pass through the semi-permeable membrane into the bicarbonate hemodialysis solutions, exit the hemodialyzer, enter the hemodialysis monitor and exit the monitor and are ultimately discarded. The ionic and molecular composition of the hemodialysis solution establishes the concentration gradient between the blood and the hemodialysis solution passing through the hemodialyzer which permits the effective removal of waste products and toxins found in excess in the patient's blood during acute and end-stage renal failure.

Since different patients have different requirements for the removal rates and quantities of various molecules and toxins (i.e. blood urea nitrogen, creatinine, potassium, phosphate, magnesium, chloride, sodium calcium water, etc.) in acute and chronic renal failure, it necessitates having a variety of different bicarbonate containing hemodialysis solutions to satisfy the needs of all acute and end-stage renal failure patients. In addition, there a number of different types of hemodialysis machines which have different proportioning rates.

TABLE I

Stream 1	Stream 2 Acidified Concentrate Proportioning Ratios	Stream 3: Bicarbonate Concentrate Proportioning Ratios
Water	1:35.83 or 1:44.00 or 1:34.00	1:19.13 or 1:27.57 or 1:25.16

The Rockwell Medical Technologies Dri-Sate™ Acid Concentrate Mixes for hemodialysis have been previously cleared for marketing in the US under a 510(k) Notification on June 16th, 1998 (510(k) Number K981003).

Rockwell Medical Technologies Dri-Sate™ Mixer**Predicate Devices:**

The Rockwell Medical Technologies Dri-Sate™ Mixer for Dri-Sate™ acid concentrate solutions is substantially equivalent to the Fresenius USA, Inc. Hemodialysis Concentration Dissolution Unit P/N 89-290-09 (510(k) Number K944493).

Examination of the information pertaining to the Rockwell Medical Technologies Dri-Sate™ Mixer demonstrates that this device is substantially 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' Dri-Sate™ Mixer is designed to mix the Rockwell Medical Technologies Dri-Sate Acid Concentrate Mixes with purified water to produce an acid concentrate solution for hemodialysis for use in 3-stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines / monitors. The Rockwell Medical Supply LLC. Dri-Sate Acid Concentrate Solutions which are mixed in the Dri-Sate Mixer™ 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 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.

Clinical Test Results:

Clinical testing was not performed



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 1999

Jeffrey R. Shideman, Ph.D.
Rockwell Medical Technologies, Inc.
28025 Oakland Oaks Court
Wixom, MI 48393

Re: K983618
Dri-Sate™ Mixer for Preparation
of Acidified Dialysate
Dated: June 15, 1999
Received: June 21, 1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 KPO

Dear Dr. Shideman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

