510K(k) SUMMARY

SUBMITTER:	**Rockwell Medical, LLC.** Rockwell Medical Supply, LLC. 28025 Oakland Oaks Wixom, MI 48393 Phone: 810-546-0040
DATE PREPARED:	**August 15th, 1997**
DEVICE NAME:	**Concentrate Solutions for Acetate Dialysate**
CLASSIFICATION NAMES:	**Concentrate Solutions for Hemodialysis** ***Accessories to Hemodialysis***
PREDICATE DEVICE:	**Dial Medical, Inc. Acetate-Based Concentrate**

OCT 30 1997

Device Description:

The Rockwell Medical Supply, LLC. Hemodialysis concentrate solutions and for acetate dialysate contain salt (acetate, sodium, calcium, potassium magnesium and chloride), sugar (dextrose), and water containing solutions formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water. These solutions 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 presented in this 510K Notification are intended to be used in two stream hemodialysis machines in which an acetate concentrate is proportioned into one stream, and a specified volume of water is proportioned into the second stream of the hemodialysis machine proportioning system. These two streams are then mixed to prepare a final proportioned hemodialysis solution. These types of a final hemodialysis solutions are commonly referred to as "Acetate 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 acetate 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 weigh 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

acetate containing 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 acetate containing hemodialysis solutions to satisfy the needs of all acute and end-stage renal failure patients. The solutions presented in this 510K Notification are designed or formulated to be used with hemodialysis machines that proportion according to the following dilution ratios:

TABLE I

Stream 1	Stream 2 Acetate Concentrate Proportioning Ratio
Water	1:34.00

It is for these reasons that a manufacturer of these hemodialysis solutions must provide a number of different formulations to contain varying concentrations of the various molecular components. The concentrations of these various molecular components are varied in the final hemodialysis solution within physiological and non-physiological ranges to permit the efficient removal of lack thereof from the patients blood during hemodialysis. Please refer to the Labeling Section of this 510K for a complete listing of each formulation.

Predicate Devices:

The Rockwell Medical Supply, LLC. Concentrate Solutions for Acetate Dialysate are substantially equivalent Dial Medical, Inc. Acetate hemodialysis bath concentrate solutions.

Examination of the information pertaining to the Rockwell Medical Supply, LLC. Acetate hemodialysis concentrate for acetate hemodialysis demonstrates that this device is substantially equivalent in composition, intended use, packaging and labeling to other acetate hemodialysis 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.

TABLE I
PREDICATE DEVICES

Device Name	Dial Medical of Florida Hemodialysis Bath Concentrate Solutions
Intended Use	Acetate Hemodialysis Bath Concentrate Solutions
510K Document Number	K864285
Approval Date	March 7, 1987
FDA Regulatory Class	II

Intended Use:

The Rockwell Medical Supply LLC. Concentrate Solutions for Acetate Dialysate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor

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 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 LLC Concentrate Solutions for Acetate 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

Rockwell Medical Supply, LLC
c/o Jeffrey R. Shideman, Ph.D.
International Medical Products Corporation
7307 Glouchester Drive
Edina, Minnesota 55435

Re: K973253
Rockwell Medical Supply, LLC, Concentrate Solutions for Acetate Dialysis
Dated: August 15, 1997
Received: August 29, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 78 KPO

Dear Dr. Shideman:

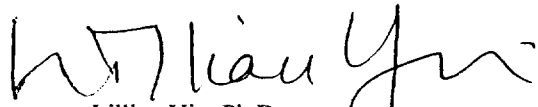
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973253

Device Name: Rockwell Medical Supply, LLC Concentrate Solutions for Acetate Hemodialysis

Indications For Use:

The Rockwell Medical Supply Concentrate Solutions for Acetate Hemodialysis are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Ratliff

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973253

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)