AUG 30 1999

RENACLEAR™ DIALYZER CLEANING SYSTEM

510(k) Summary of Safety and Effectiveness

Manufacturer: Minntech Corporation
Address: 14605 28th Avenue North
Mpls, MN 55447
USA

Official Contact: Robert Johnson
Vice President, Regulatory Affairs and Quality Assurance

Minntech Corporation has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalency of the RenaClear™ Dialyzer Cleaning System to other dialyzer pre-cleaning cycles in automated dialyzer reprocessing systems currently in distribution in the United States.

1. Device Description

The RenaClear™ Dialyzer Cleaning System facilitates the cleaning and removal of blood and other debris from multiple-use hollow fiber dialyzers prior to an institutions approved dialyzer reprocessing program. The stand-alone countertop system is equipped with two header cleaners that attach to the blood ports of a dialyzer. The header cleaners have a retractable, rotating, directional needle jet that will inject a water/air mixture into the dialyzer header and blood pathway. Simultaneously the dialyzer dialysate compartment and the exterior of the dialyzer fibers will be pressurized water to achieve reverse ultrafiltration.

The operator, through the use of a membrane switch front panel, controls the RenaClear™ Dialyzer Cleaning System. Operators have the following cycle choices: Dialyzer clean, system clean, system sanatize and system rinse.

2. Intended Use

Minntech Corporation's RenaClear™ Dialyzer Cleaning System is used to facilitate the cleaning of blood and other debris from multiple-use hollow fiber dialyzers prior to being reprocessed in a dialyzer reprocessing program.

3. Comparison to Another Device in Commercial Distribution Within the United States

The RenaClear™ Dialyzer Cleaning System is equivalent to other dialyzer pre-cleaning cycles in automated dialyzer reprocessing systems currently in distribution in the United States. The Renatron® II Dialyzer Reprocessing System

(K904210) pre-clean cycle is intended to pre-clean multiple-use dialyzers prior to testing and sterilization.

4. Summary

4.1 Minntech Corporation has performed functional testing to show the RenaClear™ Dialyzer Cleaning System is safe and has equivalent performance with respect to the predicate device.

4.2 All materials have been tested for material compatability with the chemicals used in the system as specified in the labeling.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information within the 510(k) to support the claim that the RenaClear™ Dialyzer Cleaning System is safe and effective when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 1999

Mr. Richard M. Ormsbee
Regulatory Affairs Associate
Minntech Corporation
14605 28th Avenue, N.
Minneapolis, MN 55447

Re: K991851
RenaClear™ Dialyzer Cleaning System
Dated: May 27, 1999
Received: June 1, 1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 LIF

Dear Mr. Ormsbee:

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

Indications for Use

510(k) Number (if Known): K991851

Device Name: RenaClear™ Dialyzer Cleaning System

Indications for Use:

Minntech Corporation's RenaClear™ Dialyzer Cleaning System is used to facilitate the cleaning of blood and other debris from multiple-use hollow fiber dialyzers prior to being reprocessed in an approved dialyzer reprocessing program.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per21 CFR 801.109) OR Over-the Counter-use ___ (Optional Format 1-1-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991851