DEC 4 1998

K974064

X. 510k Summary:

Trade Name - Micro X™ Residual Test Strips

Common name - Residual test strips

Classification name - Dialyzer test strips

Substantially equivalent to Renalin Residual Test Strips

Description - Micro X™ Residual Test Strips are approximately 0.25" x 4.75" packaged 100strips /container. The strips are labeled for use in Reprocessing Hemodialyzers.

Intended Use -Micro X™ Residual Test Strips are intended for use in determining the level of peracetic acid present in dialyzers at the conclusion of the required rinse procedure, and prior to the initiation of dialysis. The strips are also used for the determination of residual peracetic levels present in the rinse solution of water treatment systems and dialysis machines following sanitization/disinfection procedures.

Characteristics - Micro X™ Test Strips have a test pad, which is impregnated with peroxidase, which liberates oxygen from peracetic acid upon contact with the solution. The oxygen reacts with the chromophore, color indicator, which is also present on the test pad, resulting in a color change. The color change is compared to the color scale on the container and the result is read directly in mg/L. This is an important characteristic as levels of peracetic acid above those indicated by the germicide manufacturer may compromise dialyzer biocompatibility. This test strip, when properly used, provides a measure of residual germicide within the fluid pathways of reprocessed dialyzers.

Test Data:

Comparative testing between Micro X™ Residual Strips

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 1998

Mr. Michael Honstein
Vice President of Operations
Reprocessing Products Corporation
1661 W. Prince Rd., Suite 104
Tucson, Arizona 85705

Re: K974064
Micro X™ Residual Test Strips
Dated: September 8, 1998
Received: September 8, 1998
Regulatory Class: II
CFR 21 876.5820/Procode: 78 MSY

Dear Mr. Honstein:

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 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,

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): K974064

Device Name: MICRO-X RESIDUAL TEST STRIPS

Indications For Use:

Micro-X Residual Test Strips are intended for use as a semi-quantitative test of the residual presence of peracetic acid in dialyzers after reprocessing. This device may be used with all peroxyacetic/peracetic acid germicides used in the reprocessing of dialyzers, sanitation of water treatment systems and dialysis machine disinfection as part of an established quality assurance program.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974064

Prescription Use √ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)