

2/10/99

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K974426

X. 510k Summary:

Trade Name - Micro Xtm Potency Test Strips

Common name - Indicator test strips

Classification name - Dialyzer test strips

Substantially equivalent to Renalin Indicator Test Strips

Description - Micro Xtm Potency Test Strips are approximately 0.25" x 2.0" packaged 100strips /container. The strips are labeled for use in Reprocessing Hemodialyzers.

Intended Use -Micro Xtm Potency Test Strips are intended for use in verifying the presence of peracetic acid at the conclusion of the required exposure period for the germicide during dialyzer reprocessing, water treatment sanitization and machine disinfection.

Characteristics - Micro Xtm Potency Test Strips are impregnated with an indicator solution which is activated by the presence of peracetic acid. The reaction results in a color change of the indicator which provides visual confirmation of the presence of peracetic acid. This is an important characteristic as peracetic acid is a clear solution and can easily be confused with saline, water or other clear solutions which may have been inadvertently added to the dialyzer in place of the peracetic acid solution

While the test is not quantitative, as it does not provide a measure of concentration, it is activated above a minimum level of peracetic acid. This characteristic is exploited to provide a YES / NO indication of the presence of an appropriate level of peracetic acid.

Test Data:

Comparative testing between Micro Xtm Potency Strips, Renalin Indicator Test Strips indicate identical performance among the test strips.



FEB 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Michael Honstein
Vice President of Operations
Reprocessing Products Corporation
1661 W. Prince Rd., Suite 104
Tucson, Arizona 85705Re: K974426
Micro-X™ Potency Test Strip
Dated: October 4, 1998
Received: November 12, 1998
Regulatory class: II
21 CFR §876.5820/Product code: 78 LIF

Dear Mr. Honstein:

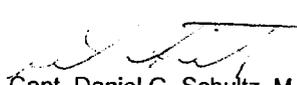
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

510(k) Number (if known): UNKNOWN

Device Name: MICRO-X POTENCY TEST STRIPS

Indications For Use:

Micro-X Potency Test Strips are intended for use as a semi-quantitative test of the 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 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)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K974426 | S⁰⁰¹