K980164

APR 16 1998

Environmental Test Systems, Inc.

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	January 15, 1998
Submitter:	Environmental Test Systems, Inc.
Address:	23575 County Road 106 Elkhart, IN 46514-0659 U.S.A. (219) 262-2060
Contact:	Bruce G. Piekarski, Director-Business Development
Device Trade/ Proprietary Name:	SteriChek™ Peracetic Acid Reagent Strips
Device Common Name:	ETS Peracetic Acid Reagent Strips
Classification Name:	Class II CH
Predicate Device:	Serim™ Peracetic Acid Reagent Strips Manufactured by Environmental Test Systems, Inc. (for Serim Research Corporation)
Device Description:	The device is made up of a 0.20 inch square faint-yellow reagent pad that has been chemically treated to detect peracetic acid in dialyzer reprocessing mix. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.
Intended Use:	SteriChek Peracetic Acid Reagent Strips provide a convenient means for determining the effective levels of peracetic acid in dialyzer reprocessing. The chemically treated pad changes color relative to the amount of peracetic acid in the dialyzer reprocessing mix.

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Technological Characteristics:	The concentration of peracetic acid in dialyzer reprocessing is obtained by observing the absence or concentration of color. None or minimal color after 10 seconds indicates insufficient levels of peracetic acid and dark color (gray/purple) or black indicates acceptable levels of peracetic acid. SteriChek™ Peracetic Acid Reagent Strips contain starch, potassium iodide and a pH buffer. When reacted with peracetic acid, the iodide is oxidized to iodine, forming a gray/purple color with starch.
Assessment of Performance:	The predicate device has been manufactured by Environmental Test Systems, Inc. since its introduction by Serim Research Corporation. ETS will manufacture the SteriChek™ Peracetic Acid Strips using the same manufacturing and quality assurance procedures to produce a product identical in performance to the marketed device, but with a new name. The change in formulation provides for different color development but follow the same test principles as the predicate device.
Conclusion:	The SteriChek™ Peracetic Acid Reagent Strips have the same intended use as the predicate device. There will be no changes in the design, materials, or other features compared to the predicate device, other than a change in color development and the trade or proprietary name of the device. The SteriChek™ Peracetic Acid Reagent Strips have no technological characteristics that raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Bruce G. Piekarski
Director-Business Development
Environmental Test Systems, Inc.
P.O. Box 4659
Elkhart, IN 46514-0659

Re: K980164
SteriChek™ Peracetic Acid Reagent Strips
Dated: January 15, 1998
Received: January 16, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 MSY & LIF

Dear Mr. Piekarski:

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) _____

Device Name: SteriChek™ Peracetic Acid Regent Strips

Indications for Use:

SteriChek™ Peracetic Acid Reagent Strips provide a convenient means for determining the effective levels of peracetic acid in dialyzer reprocessing in hemodialysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K98-0164

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