



Environmental Test Systems, Inc.

K974798

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: December 12, 1997

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™ Residual Peroxide Reagent Strips**

Device Common
Name: ETS Peroxide Reagent Strips

Classification Name: Class II
CH

Predicate Device: Serim™ Peroxide Reagent Strips
Manufactured by Environmental Test Systems, Inc. (for Serim Research Corporation)

Device Description: The device is made up of a 0.20 square inch off-white reagent pad that is chemically treated to detect peroxide in water. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.

Intended Use: SteriChek™ Peroxide Reagent Strips provide a convenient means for measuring the concentration of peroxide remaining in water being used to rinse out dialysate lines and dialyzers following disinfection with peroxide/peracetic acid. The chemically treated pad changes color relative to the amount of peroxide remaining in the rinse.

K 974798

P2092

SteriChek Residual Peroxide Reagent Strips
510(k) Safety and Effectiveness Summary - December 12, 1997
Environmental Test Systems, Inc. (Page 2 of 2)

**Technological
Characteristics:**

The concentration of peroxide in rinse water is obtained by comparing the color of the reagent pad with color blocks on the label. The color blocks are calibrated in terms of peroxide concentration in parts per million (ppm). The device is used as a rapid screening method to detect levels of less than 1.0 ppm, or as a quantitative method to allow estimation of peroxide concentration between 0 and 10 ppm.

SteriChek™ Residual Peroxide Reagent Strips contain 4-aminoantipyrine (4AAP) and 8-amino-2-naphthalene sulfonic acid (ANS), two colorless compounds which serve as the indicator system, peroxidase and a pH buffer. The reaction of the indicator reagents with hydrogen peroxide is catalyzed by peroxidase. This reaction of the indicators gives rise to a red-purple color. The intensity of the color is proportional to the concentration of the peroxide.

**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™ Residual Peroxide Reagent 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 follows the same test principles as the predicate device.

Conclusion:

The SteriChek™ Residual Peroxide 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 the change of indicators and the trade or proprietary name of the device. The SteriChek™ Residual Peroxide Reagent Strips have no technological characteristics that raise new types of safety or effectiveness questions.



MAR 20 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Bruce G. Piekarski
Director - Business Development
Environmental Test Systems, Inc.
P.O. Box 4659
Elkhart, IN 46514-0659Re: K974798
SteriChek™ Residual Peroxide Reagent Strips
Dated: December 19, 1997
Received: December 22, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 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

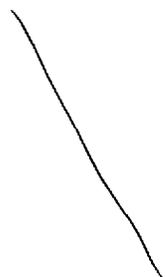
SteriChek Residual Peroxide Reagent Strips
510(k) Submission - December 12, 1997
Environmental Test Systems, Inc.

510(k) Number (if known) _____

Device Name: SteriChek™ Residual Peroxide Regent Strips

Indications for Use:

SteriChek™ Residual Peroxide Reagent Strips provide a convenient means for measuring the concentration of peroxide remaining in water being used to rinse out dialysate lines and dialyzers following disinfection with peroxide/peracetic acid.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dale R. Sattler
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number *K974798*

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use