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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	December 10, 1999
Submitter:	Environmental Test Systems, Inc.
Address:	23575 County Road 106 Elkhart, IN 46514 U.S.A. (219) 262-2060
Contact:	David A. Morris, Ph.D. Vice President, Technology
Device Trade/ Proprietary Name:	**SteriChek™ Chlorine Reagent Strips**
Device Common Name:	Total Chlorine Reagent Strips
Classification Name:	Class II CH
Predicate Device:	Serim™ HiSense Test Kit
Device Description:	The device is made up of a 0.20 inch square off-white reagent pad that has been chemically treated and affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip. The reagent pad is activated by exposing it to the sample. The color of the pad is visually compared to a color chart to determine the amount of total chlorine present in the sample.
Intended Use:	SteriChek™ Total Chlorine Reagent Strips provide a quick convenient means of testing for low levels of total chlorine (i.e. total chloramines plus free chlorine) in water used to prepare dialysate. The color that develops in the pad after exposure to the sample according to the directions is compared to a color chart to determine the concentration of total chlorine present in the sample.
Technological Characteristics:	The concentration of chlorine in rinse water is obtained by comparing the

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color of the reagent pad with color blocks on the label. The color blocks are calibrated in terms of chlorine concentration in parts per million (ppm). The device is used as a quantitative method to detect total chlorine concentrations between 0 and 3 ppm. The device will reliably measure total chlorine concentrations as low as 0.1 ppm total chlorine.

SteriChek™ Chlorine Reagent Strips contains an indicator, Michler's thioketone, an activating surfactant, and other non-reactive ingredients. Free chlorine and combined chlorine (chloramines) react with the indicator to form a blue complex. The amount of the blue complex is dependent on the concentration of free chlorine and combined chlorine in the sample.

Assessment of Performance: The performance characteristics of SteriChek™ Total Chlorine reagent Strips Serim™ and HiSense Test Kit were analyzed with water samples in which either sodium hypochlorite or chloramines were added to give a range of free chlorine or combined chlorine levels. The performance was equivalent.

Conclusion: The SteriChek™ Total Chlorine Reagent Strips have the same intended use as the predicate device. The predicate device's indicator system (qualitative combined dry and liquid colorimetric method) is different than that of the Total Chlorine Reagent Strips. However, both systems effectively measure the total free and combined chlorine levels in water. The SteriChek™ Total Chlorine 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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David A. Morris, Ph.D.
Vice President, Technology
Environmental Test Systems, Inc.
23575 County Road, #106
Elkhart, IN 46514

Re: K994226
SteriChek™ Total Chlorine Reagent Strips
Dated: March 1, 2000
Received: March 6, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 MSY

Dear Dr. Morris:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known) K994226

Device Name: SteriChek™ Total Chlorine Reagent Strips.

Indications for Use:

SteriChek™ Total Chlorine Reagent Strips provide a quick convenient means of testing for low levels of total chlorine (i.e. total chloramines and free chlorine) in water used to prepare dialysate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994226