4/2/99

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SteriChek™
REAGENT STRIPS

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	November 5, 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™ Total Chlorine Test Kit**
Device Common Name:	ETS DPD Chlorine Test Kit
Classification Name:	Class II CH
Predicate Device:	Serim™ HiSense Test Strips
Device Description:	The device consists of utilizing a fixed sample size of powdered reagent with a predetermined water sample volume in a test tube to effect a color reaction in the water sample. The color of the sample is then visually compared to a colormetric comparator to determine the total chlorine level in the sample. The device utilizes a recognized standard method of analysis for determining levels of total chlorine in water according to the Association for the Advancement of Medical Instrumentation (1993 Association for the Advancement of Medical Instrumentation-ANSI/AAMI;RD5-1992).
Intended Use:	SteriChek™ Total Chlorine Test Kit provides 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 water sample changes color relative to the amount of total chlorine in the water sample.

Technological Characteristics:

The concentration of total chlorine in water is obtained by comparing the color of the water sample mixed with the powdered reagent to the color comparator. The color comparator is calibrated in terms of total chlorine concentration in parts per million (ppm). The device is used as a quantitative method to detect total chlorine concentrations between 0 and 0.7 ppm.

SteriChek™ Total Chlorine Test Kit contains DPD and potassium iodide that serves as the indicator system and a pH buffer. Chlorine oxidizes DPD (a colorless compound) to form a magenta (red) color. Chloramines oxidize potassium iodide to iodine, which oxidizes DPD to form the magenta color. The intensity of the color is proportional to the concentration of total chlorine (chloramines and free chlorine).

Assessment of Performance:

The performance characteristics of the predicate device was analyzed with water samples in which either sodium hypochlorite or monochloramines were added to give a range of free chlorine or combined chlorine levels (See Predicate Device "Product Insert"). The SteriChek™ Total Chlorine Test Kit was also analyzed with samples in which either sodium hypochlorite or monochloramines were added to give a range of free chlorine or combined chlorine levels. Performance of both devices was equivalent.

Conclusion:

The SteriChek™ Total Chlorine Test Kit has the same intended use as the Predicate Device. The predicate device's indicator system (qualitative combined dry and liquid reagent colorimetric method) is different than SteriChek™ Total Chlorine Test Kit (quantitative powdered reagent colorimetric method). However, SteriChek™ Total Chlorine Test utilizes the recognized standard method of analysis of the Association for the Advancement of Medical Instrumentation. In fact, the SteriChek™ Total Chlorine Test Kit has 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

APR 2 1999

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

Re: K983997
SteriChek™ Total Chlorine Test Kit
Dated March 5, 1999
Received: March 8, 1999
Regulatory Class: II
21 CFR 876.5665/Procode: 78 MSY and 78 FIP

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 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) _____

Device Name: SteriChek™ Total Chlorine Test Kit

Indications for Use:

SteriChek™ Total Chlorine Test Kit provides 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)

[signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983997/S004