K971598

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

JUL 18 1997

Prepared: April 29, 1997

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, Research

Device: Trade/Proprietary Name: **SteriChek™ Chlorine Reagent Strips**
Common/Usual Name: Test Strip for Chlorine in water

Classification Name: Class II
CH

Predicate Device: Serim™ Chlorine 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 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.

Intended Use: SteriChek™ Chlorine Reagent Strips provide a convenient means for measuring the concentration of chlorine bleach remaining in water being used to rinse out dialysate lines following disinfection of hemodialysis equipment.

Technological Characteristics: The concentration of chlorine 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 chlorine concentration in parts per million (ppm). The device is used as either a 5 second rapid screening method to detect levels above 0.5 ppm, or as a 30 second quantitative method to allow estimation of chlorine concentrations between 0 and 5 ppm.

SteriChek™ Chlorine Reagent Strips contain syringaldazine, a colorless compound which serves as an indicator, potassium iodide, and a pH buffer.

The reagent strips react with both free chlorine and combined chlorine

(monochloramines). Free chlorine oxidizes syringaldazine to form a colored oxidation product. Combined chlorine in the form of monochloramines oxidize potassium iodide to iodine which in turn oxidizes syringaldazine to the colored form.

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™ Chlorine Reagent Strips using the *same bill of materials* and the *same manufacturing and quality assurance procedures* to produce a product *identical in performance* to the marketed device, but with a new name.

Conclusion:

The SteriChek™ Chlorine 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 the trade or proprietary name of the device. The SteriChek™ 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

JUL 18 1997

David A. Morris, Ph.D.
Vice President, Research
Environmental Test Systems, Inc.
P.O. Box 4659
Elkhart, Indiana 46514-0659

Re: K971598
SteriChek™ Chlorine Reagent Strips
Dated: May 1, 1997
Received: May 2, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 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 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 requirement, 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/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™ Chlorine Reagent Strips.

Indications for Use:

SteriChek™ Chlorine Reagent Strips provide a convenient means for measuring the concentration of chlorine bleach remaining in water being used to rinse out dialysate lines following disinfection of hemodialysis equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Ratliff

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971598

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