DEC 2 3 2003

K031267

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	April 18, 2003
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. Director of Technology
Device Trade/ Proprietary Name:	SteriChek® Bicarb pH Reagent Strips
Device Common Name:	Bicarb pH Reagent Strips
Classification Name:	Class II CH
Predicate Device:	Serim™ Bicarb pH II Test Strips
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 pH of the bicarbonate solution.
Intended Use:	SteriChek® Bicarb pH Reagent Strips provide a quick convenient means of checking the pH of the bicarbonate solution of used to prepare dialysate or concentrated bicarbonate solution used in the preparation of 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 pH of the sample.
Technological Characteristics:	The pH of the bicarbonate solution or bicarbonate concentrate is obtained by comparing the color of the reagent pad with color blocks on the label.

The color blocks are calibrated in terms of pH values. The device is used to measure the pH of bicarbonate solutions and concentrated bicarbonate solutions.

SteriChek® Bicarb pH Reagent Strips contains the indicators, Cresol Red and Phenol Red. The indicators undergo a color change that is dependent on the pH or hydrogen ion concentration of the sample.

Assessment of Performance:

The performance characteristics of SteriChek® Bicarb pH Reagent Strips and Serim™ Bicarb pH II Test Strips were analyzed with acid/bicarbonate solutions and concentrated bicarbonate solutions. Acid/bicarbonate solutions were prepared through adjustment of acidic and basic components to give discrete pH levels. Concentrated bicarbonate solutions were prepared through progressive conversion of the sodium bicarbonate to its carbonate form by aging. A standard reference method with calibration based on NIST traceable standard reference material was used to determine the reference pH values. The performance was equivalent.

Conclusion:

The SteriChek® Bicarb pH Reagent Strips have the same intended use as the predicate device. The predicate device's indicator system is different than that of the Bicarb pH Reagent Strips. However, both systems effectively measure the pH or hydrogen ion concentration of bicarbonate solutions. The SteriChek® Bicarb pH 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

DEC 2 3 2003

David A. Morris, Ph.D.
Director, Research
Environmental Test Systems, Inc.
P.O. Box 4659
ELKHART IN 46514-0659

Re: K031267
Trade/Device Name: SteriChek® Bicarb pH Reagent Strips
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 MNV
Dated: August 29, 2003
Received: September 29, 2003

Dear Dr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K031267

Device Name: SteriChek® Bicarb pH Reagent Strips.

Indications for Use:

SteriChek® Bicarb pH Reagent Strips provide a quick convenient means of checking the pH of bicarbonate solution used to prepare dialysate and concentrated bicarbonate solutions used in the preparation of 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)

David A. Lepmann
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031267