



K972035

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AUG 29 1997

**510(k) SUMMARY**

**SPOROX™ Test Strips**

**SUBMITTED BY:**

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Serim Research Corporation  
P.O. Box 4002  
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Contact Person: James E. Christner

Date Prepared: May 29, 1997

*James E. Christner*  
*May 29, 1997*

**DEVICE NAME:**

Trade Name: SPOROX™ Test Strips  
Common Name: Test Strips for Hydrogen Peroxide in SPOROX™  
Sterilizing and Disinfecting Solution  
Classification  
Name: Chemical Sterilization Process Indicator

**LEGALLY MARKETED EQUIVALENT DEVICE**

This product is similar in design, composition, and function to the Peracetic Acid Reagent Strips manufactured by Serim Research Corporation which was the subject of Premarket Notification #K910320A. The product is similar in utility to a titrimetric assay. Supportive data for substantial equivalence to the latter was obtained.

**DESCRIPTION OF THE SPOROX™ TEST STRIP:**

The SPOROX™ Test Strips consist of a 0.2 x 0.2 inch reagent-containing pad attached to one end of a 0.2 x 3.25 inch polystyrene handle. The reagent pad is immersed in the sample for five seconds. The strip is rotated to a vertical position with the pad up to allow excess sample to drain by gravity and then is covered with a chamber to prevent sample evaporation. The reagent pad is observed 15 minutes after immersion. If the pad is completely brown/black, the SPOROX™ Sterilizing and

Disinfecting Solution contains hydrogen peroxide at concentrations greater than 6.0% (the minimum effective concentration or MEC). If the SPOROX™ Sterilizing and Disinfecting Solution contains hydrogen peroxide at concentrations of 6.0% or less, a distinct white area forms in the center of the pad.

The reagent pad contains iodide and starch plus a reducing compound that prevents visible reaction when the hydrogen peroxide concentration is at or below the MEC. When the peroxide level is in sufficient excess of the MEC, the surplus oxidizes the iodide to iodine which in turn forms a dark-colored complex with the starch.

**INTENDED USE:**

SPOROX™ Test Strips provide a rapid, convenient, semi-quantitative means of indicating whether effective concentrations of hydrogen peroxide are present in SPOROX™ Sterilizing and Disinfecting Solution. The SPOROX™ Test Strips indicate concentrations of hydrogen peroxide but do not confirm disinfection or sterilization.

**TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:**

SPOROX™ Test Strips are used for determining hydrogen peroxide levels in SPOROX™ Disinfecting and Sterilizing Solution whereas the Serim Peracetic Acid Reagent Strips are used for determining peracetic acid levels in disinfectants employed in hemodialyzer reprocessing. Both tests consist of dry reagent-containing paper pads attached to plastic handles. Both contain a reducing compound which prevents visible reaction at ineffective concentrations of active ingredient and a starch/iodide indicator. Both give PASS/FAIL results. Completely colored reagent pads indicate effective levels of germicide. When the disinfectant solutions are at or below their MEC values, white areas are visible on the reagent pads.

**STATEMENT OF SUBSTANTIAL EQUIVALENCE:**

SPOROX™ Test Strips from three trial production lots were used by seven participants in blind studies to test SPOROX™ standards assayed by a titrimetric procedure. At 6.05% hydrogen peroxide, 0 out of 168 results were PASS, giving a test specificity (lack of false PASS results) of 1.00. At hydrogen peroxide concentrations of 6.58% and 7.00% respectively, 41 out of 84 and 165 out of 168 results were PASS. These results show that the SPOROX™ Test Strips effectively indicate when the hydrogen peroxide concentration in SPOROX™ Disinfecting and Sterilizing Solution is at or below its MEC of 6.0%.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert C. Boguslaski, Ph.D.  
President  
Serim Research Corporation  
P.O. Box 4002  
Elkhart, Indiana 46514-0002

AUG 29 1997

Re: K972035  
Trade Name: Sporox Test Strips  
Regulatory Class: II  
Product Code: JOJ  
Dated: May 29, 1997  
Received: June 2, 1997

Dear Dr. Boguslaski:

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.

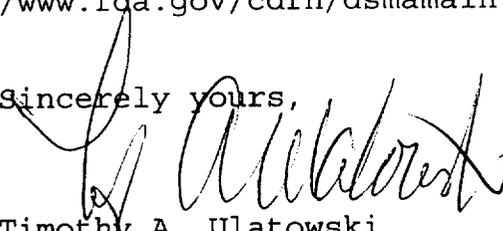
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4618. 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: SPOROX™ Test Strips

Indications For Use:

**SPOROX™ Test Strips** provide a rapid, convenient semi-quantitative means of indicating whether effective concentrations of hydrogen peroxide are present in **SPOROX® Sterilizing and Disinfecting Solution**. The SPOROX™ Test Strips indicate concentrations of hydrogen peroxide but do not confirm disinfection or sterilization.

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

\_\_\_\_\_  
Concurrence of CDH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K972035

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

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