RECKITT & COLMAN INC.

SECTION 4

K970230

510(k) SUMMARY

OCT 29 1997

SPOROX®

RECKITT & COLMAN INC.
225 SUMMIT AVENUE
MONTVALE, NJ 07645

Date: October 24, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21CFR§807.92 as delineated in the Federal Register, Vol. 59, No. 239, pg 6428 ff, December 14, 1994.

1.0 Contact Person:

Ms. Eileen J. Moyer
Director of Regulatory Affairs
Reckitt & Colman Inc.
1 Philips Parkway
Montvale, NJ 07645

Phone: (201)573-6314
Fax: (201)573-6046

2.0 Name of Device:

Trade Name:	Sporox®
Common Name:	Hydrogen Peroxide
Classification name(s):	Liquid Chemical Sterilant / high level disinfectant (MED) Unclassified

3.0 Predicate Device:

Cidex® Formula 7 Long-Life Activated Dialdehyde Solution, manufactured by Johnson & Johnson (K924334).

4.0 Description of Devices:

Sporox is a nominal 7.5% hydrogen peroxide solution, buffered with phosphoric acid. Hydrogen peroxide, the active ingredient in Sporox,® exerts its germicide via a strong oxidation reaction of cellular components.

5.0 Intended Use:

Sporox® is intended to be used as a ready-to-use liquid chemical sterilant for the sterilization or high-level disinfection of heat-sensitive medical equipment for which alternative methods of terminal reprocessing are not suitable or available.

6.0 Technological Characteristics:

Both Sporox® and the predicate device, Cidex,® are liquid chemical sterilants for sterilization or high-level disinfection of heat-sensitive medical equipment for which alternative methods of terminal reprocessing are not suitable or available. They differ primarily in their active ingredient, the need for activation, contact conditions and reuse period. Cidex's active ingredient is 2.5% dialdehyde and, unlike Sporox,® it requires activation. The contact time as a sterilant is 6 hours at 20°C for Sporox,® and 10 hours at 25°C for Cidex®. The contact time for disinfection is 30 minutes at 20°C for Sporox® and 90 minutes at 25°C for Cidex.® Finally, Sporox® can be reused for up to 21 days and Cidex® can be reused for up to 28 days.

6.1 Nonclinical Tests (Toxicity / Stability)

Reckitt & Colman conducted testing that demonstrated Sporox's bactericidal, fungicidal, virucidal, sporicidal, and tuberculocidal activity, utilizing appropriate AOAC use dilution, fungicidal, tuberculocidal and sporicidal methods. Additionally, the Company conducted acute dermal toxicity, acute oral toxicity, primary skin irritation, in-vitro hemolysis, primary eye irritation, neutral red uptake bioassay, and 28-day oral toxicity testing, consistent with FDA's guidance on biocompatibility testing. See FDA, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, #G95-1 (May 1, 1995). These tests demonstrated the product's safety for use as a liquid chemical sterilant. The Company also conducted stability studies demonstrating the product has a minimum of two years stability if unopened and stored according to label instruction, and that the product can be reused for up to 21 days when used at 20°C according to label instructions.

RECKITT & COLMAN INC.

6.2 Device / Material Compatibility Studies

The Company demonstrated the compatibility of Sporox® with medical devices and device materials, as set forth in the product's labeling, by conducting studies with actual devices, in both simulated use and clinical applications, and by conducting a rigorous evaluation of a number of difference plastics, metals, and elastomers commonly used in medical devices and noted in the product label. The materials were exposed to a Sporox® solution, containing 7.42% hydrogen peroxide content for 500 hours at 20°C (equivalent to 1000 disinfectant cycles).

6.3 Residue Testing

The Company conducted testing consistent with FDA's "Guidance on the Content and Format of 510(k) Submission for Liquid Chemical Germicides," demonstrating extremely low levels of residuals associated with reprocessing of even very complex medical devices. The levels were significantly below levels which are expected to induce toxic or harmful effects.

6.4 Actual Use Testing

Reckitt & Colman Inc. has submitted actual use testing and information that demonstrates the safety and efficacy of Sporox® for use as a liquid chemical sterilant. The company has submitted testing for Sporox® utilizing endoscopes after patient use and using inoculated endoscopes. The product was marketed previously for thirteen years with no experience of adverse effects. Documentation of Sporox® use by the Mayo Clinic in the clinical setting was submitted by the company.

The above nonclinical and device/material compatibility studies demonstrate that Sporox® is as safe and effective as Cidex® Formula 7 Long-Life Activated Dialdehyde Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Eileen J. Moyer
Director of Regulatory Affairs
Reckitt & Colman, Incorporated
One Philips Parkway
Montvale, New Jersey 07645-1575

OCT 29 1997

Re: K970230
Trade Name: Sporox®
Regulatory Class: Unclassified
Product Code: MED
Dated: October 16, 1997
Received: October 17, 1997

Dear Ms. Moyer:

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) 594-4618. 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: K970230

DEVICE NAME: Sporox® Sterilizing & Disinfecting Solution

INDICATIONS FOR USE:

Sporox® Sterilizing & Disinfecting Solution is a ready-to-use liquid chemical germicide. The product is a 7.5% nominal hydrogen peroxide solution buffered with phosphoric acid. The minimum effective concentration (MEC) is 6%. Sporox® Sterilizing and Disinfecting Solution is intended for use in the high level disinfection of heat sensitive medical equipment using the prescribed contact conditions. Devices must be soaked for 30 minutes at 20°C to high level disinfect. Sporox® may be reused for up to 21 days in conjunction with the use of an appropriate chemical indicator strip.

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

CONCURRENCE OF CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K970230

Prescription Use _____ OR Over-the-Counter Use X

(Per 21 CFR§801.109)