

3/30/99

Attachment 4

K990703

510(k) Summary

SPOROX® II

**Reckitt & Colman Inc.
1655 Valley Road
Wayne, NJ 07474**

1.0 Contact Person:

Mr. Sean McNear
Senior Regulatory Affairs Specialist
Reckitt & Colman Inc.
1800 Valley Road
Wayne, NJ 07474

Phone: 973-686-7390
Fax: 973-686-7396

2.0 Name of Device:

Trade Name: SPOROX® II
Common Name: Hydrogen Peroxide
Classification names: Liquid Chemical Sterilant / High Level Disinfectant (MED)
Unclassified (proposed class II)

3.0 Predicate Device:

The predicate device is SPOROX® Sterilizing & Disinfecting Solution
510(k) #- K970230 (1997) Marketed by Reckitt & Colman Inc.

4.0 Description of Device

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

Continued on next page

5.0 Intended Use:

SPOROX® II has the same intended use as SPOROX®. SPOROX® II 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:

SPOROX® II is similar to the predicate device SPOROX®. SPOROX® II has the same active ingredients as SPOROX®. The only difference between the two products is in the inactive ingredients of the corrosion inhibitor system. SPOROX® II has an improved corrosion inhibitor system that offers compatibility with materials and medical devices that contain copper and brass. SPOROX® II and SPOROX® are substantially equivalent in the safety and efficacy profiles.

Reckitt & Colman Inc. has conducted confirmatory testing that demonstrated SPOROX® II has equivalent antimicrobial efficacy to the predicate device, SPOROX®. The studies utilized appropriate AOAC and EPA methodology. The Company also conducted stability studies demonstrating that SPOROX® II like SPOROX® has a minimum of two years stability if unopened and stored according to label instructions, and that the product can be reused for up to 21 days when used at 20°C according to label instructions.

Additionally, as it did with SPOROX®, the Company conducted acute dermal toxicity, acute oral toxicity, primary eye irritation, primary skin irritation, skin sensitization, in-vitro hemolysis, neutral red uptake cytotoxicity assay, and 28 day repeat dose oral toxicity testing. These tests demonstrated that SPOROX® II has a substantially equivalent safety profile to SPOROX® for use as a liquid chemical sterilant and a high level disinfectant.

The Company confirmed compatibility with medical devices equivalent to the predicate device, by conducting a rigorous evaluation on a number of different plastics, metals, and elastomers commonly used in medical devices and noted in the product label. In addition, the Company determined compatibility with materials made with copper and brass which is consistent with FDA's Guidance on The Content and Format of Premarket Notification on [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants. The materials were exposed to a SPOROX® II solution, containing 7.3% hydrogen peroxide content for 500 hours at 20°C (equivalent to 1000 disinfectant cycles).

Conclusion

Reckitt & Colman Inc. have demonstrated that SPOROX® II is as safe and effective as the predicate device, SPOROX®.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1999

Mr. Sean McNear
Senior Regulatory Affairs Specialist
Reckitt & Colman, Inc.
1655 Valley Road
P.O. Box 943
Wayne, New Jersey 07474-0943

Re: K990703
Trade Name: SPOROX® II Sterilizing and
Disinfecting Solution
Regulatory Class: Unclassified
Product Code: MED
Dated: March 3, 1999
Received: March 4, 1999

Dear Mr. McNear:

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.

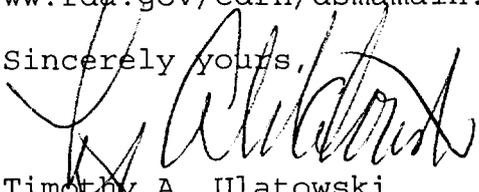
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

Page 2 - Mr. Sean McNear

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) 594-4692. 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" (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

Attachment 2

Indications for Use Statement

**510(k)
Number**

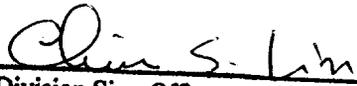
K990703

Device Name

SPOROX® II Sterilizing & Disinfecting Solution

**Indications for
Use**

SPOROX® II 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 II® Sterilizing & 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 II® may be reused for up to 21 days in conjunction with the use of an appropriate chemical indicator strip.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990703

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 X