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STERIS®

SEP - 2 2008

510(k) Summary
For
Resert™ XL HLD High Level Disinfectant

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Summary Date: June 05, 2008

1. Device Name

Trade Name:	Resert™ XL HLD High Level Disinfectant
Common/Usual Name:	Liquid Chemical Sterilants/Disinfectants
Classification Name:	Liquid Chemical Sterilants/Disinfectants
Classification Number:	21 CFR 880.6885
Product Code:	MED.

2. Predicate Device

SPOROX® Sterilizing and Disinfecting Solution (K970230) manufactured by Rickitt & Colman, Inc.

3. Description of Device

Resert XL HLD High Level Disinfectant is a nominal 2.0% hydrogen peroxide solution, buffered with furoic acid and phosphorous acids. Hydrogen peroxide is the active ingredient in Resert XL HLD, which exerts its germicidal action via a strong oxidation reaction of cellular components.

4. Intended Use

Resert™ XL HLD is a ready to use liquid chemical germicide. The product is a 2.0% nominal hydrogen peroxide solution. The minimum recommended concentration (MRC) is 1.5%. Resert XL HLD is intended to be used by health care practitioners in clinical settings as a ready to use liquid chemical disinfectant for the high level disinfection of semi-critical medical devices for which alternative methods of terminal reprocessing are not suitable or available.

High Level Disinfectant: Resert™ XL HLD High Level Disinfectant is a high level disinfectant when used or reused undiluted for a maximum of 21 days at a minimum temperature of 20°C (68°F) for a minimum immersion time of 8 minutes.

5. Description of Safety and Substantial Equivalence

Both Resert XL HLD High Level Disinfectant and SPOROX Sterilizing and Disinfecting Solution (SPOROX) formulations have common features and use indications. Their active ingredient is hydrogen peroxide. The major difference is

that Resert XL HLD has a nominal 2.0% hydrogen peroxide solution, buffered with furoic acid and phosphorous acids, while SPOROX has a 7.5% nominal hydrogen peroxide concentration, buffered with phosphoric acid, and they have high level disinfection contact times of 8 minutes and 30 minutes respectively.

The Resert XL HLD High Level Disinfectant has the same technological characteristics (i.e., design, material, chemical composition) as the predicate SPOROX device.

6. Device Comparison Table

A summary of the technological characteristics of the Resert XL HLD High Level Disinfectant in comparison to those of the predicate device is shown in Table 5-1.

Table 5-1. Comparison Matrix for Resert XL HLD and SPOROX

Feature	Resert XL HLD	SPOROX
Intended Use	Resert XL HLD is intended to be used by health care practioners in clinical setting as a high level disinfectant when used according to the labeled specified directions	SPOROX is intended to be used by health care practioners in clinical setting as a Liquid chemical sterilant and/or high level disinfectant when used according to the labeled specified directions
Active Ingredient	2.0% hydrogen peroxide	7.5% hydrogen peroxide
Surfactants	Yes	Yes
Corrosion Inhibitor	Yes	Yes
Dilution required	No	No
Contact Time – High Level Disinfection	8 minutes @ 20°C	30 minutes @20°C
Use-Reuse Period	21 days	21 days
Accessories	Resert Chemical Indicator	SPOROX Chemical Indicator
Primary Packaging	4 Liter Polyethylene bottle	1 gal. Polyethylene bottle
Secondary Packaging	4-4 Liter bottles per case	4-1 gal bottles per case
Closure System	Vented	Vented
Storage Conditions	Cool dry place	Cool dry place
Shelf-life	1 year un-opened	2 years un-opened

7. Performance Testing Summary - Bench

All AOAC/EPA Potency testing was conducted with Resert XL HLD solution, formulated to below the minimum manufacturing specification for hydrogen

peroxide, stressed to the end of its 21 day reuse life, and challenged with 5% organic challenge and 400 ppm hard water. The testing demonstrated the bactericidal, fungicidal, virucidal, sporicidal and tuberculocidal efficacy of Resert XL HLD, utilizing appropriate test methods. Also, Resert XL HLD was assessed for acute dermal toxicity, acute oral toxicity, primary skin irritation, skin sensitization, primary eye irritation, mutagenicity, and residue toxicity, according to the FDA Guidance on biocompatibility testing.

A stability program has been implemented to demonstrate a shelf-life for Resert XL HLD of at least 1 year, if unopened and stored according to label instructions, and reused for up to 21 days at a minimum temperature of 20°C (68 °F).

The test method criteria and a summary of results are presented in Tables 5-2 and 5-3.

Table 5-2. Comparison Matrix for Resert XL HLD and SPOROX Microbiological Efficacy Testing

Test Method	Resert XL HLD	SPOROX
AOAC Sporicidal Test *Bacillus subtilis* *Clostridium sporogenes*	Meets sporicidal efficacy requirements	Same
AOAC Use-Dilution Test *Pseudomonas aeruginosa* *Staphylococcus aureus* *Salmonella enterica*	Stressed solution is bactericidal	Same
AOAC Fungicidal Test *Trichophyton mentagrophytes*	Stressed solution is fungicidal	Same
EPA Virucidal Test *Poliovirus Type I* *Herpes Simplex Type 1* *Adenovirus Type 5*	Stressed Solution is virucidal	Same
Tuberculocidal Activity Test *Mycobacterium terrae*	Stressed solution is tuberculocidal	Same (*M. bovis*)
Simulated Use Test *Mycobacterium terrae*	Meets efficacy requirements	Same

Table 5-3. Comparison Matrix for Resert XL HLD and SPOROX Toxicological Evaluation

Toxicology Test	Resert XL HLD	SPOROX
Primary dermal Irritation	Slight irritant	Moderate irritant
Acute Dermal Toxicity	Dermal LD_{50} >5000 mg/kg body weight	Dermal LD_{50} > 5000 mg/kg body weight
Ocular Irritation	Mild irritant	Severe irritant
Acute Oral Toxicity	OralLD_{50} >5000 mg/kg body weight	OralLD_{50} >5000 mg/kg body weight
Skin sensitization	Non-sensitizing	Non-sensitizing
Bacterial Reverse Mutation Assay (Mutagenicity Ames Test)	Non-mutagenic	Non-mutagenic

8. Device /Material Compatibility Studies

STERIS Corporation demonstrated the material compatibility of Resert XL HLD with medical devices and device materials, as identified in the product labeling, by conducting studies with actual devices, in both Simulated and In Use applications, and by conducting rigorous evaluations of a number of different plastic, metals, and elastomers commonly used in the construction of medical devices. The materials were exposed to Resert XL HLD solution, formulated above its maximum manufacturing specification for hydrogen peroxide, for up to 134 hours at 25±2°C (equivalent up to 1005 disinfectant cycles). A comparison of the compatible and incompatible materials for Resert XL HLD and the predicate device is shown in Table 5-4.

Table 5-4. Comparison Matrix for Resert XL HLD and SPOROX Material Compatibility

Materials Compatible	Resert XL HLD	SPOROX
Plastics:		
Teflon	X	X
Polyester	X	X
Polystyrene	X	X
Polycarbonate	X	X
Polypropylene	X	X
Acrylic	X	X
Polyvinyl Chloride (PVC)	X	X
Acrylonitrile- butadiene-styrene (ABS)	X	X
Nylon	X	X
Metals:		
Stainless Steel (302,316, 410)	X	X
Chrome Plate (Steel)	X	X

Materials Compatible	Resert XL HLD	SPOROX
Platinum	P	X
Aluminum	X	X
Anodized Aluminum (6061)	X	X
Gold Plated Steel	X	P
Mild Steel	X	P
Solder 70/30	X	P
Nickel-Silver Alloy	P	N
Monel S	N	X
Brass	N	N
Copper	N	N
Nickel-Plated Steel	N	N
Tungsten Carbide	N	P
Silver	N	P
Elastomers:		
Polyurethane	X	X
Neoprene	X	X
Silicone rubber	X	X
Ethylene Propylene Diene Terpolymer (EPDM)	X	X
Viton A	X	P
Red Natural Rubber	X	X
Black Natural Rubber	P	X

X= Compatible, N= Not Compatible, P= Not Performed

Material compatibility was confirmed with two Fujinon and Olympus flexible colonoscope sets, which included procedural and cleaning/reprocessing accessories. The devices were immersed in Resert XL HLD for 134 hours (1005 cycles) at 25 ±2°C, and showed no significant cosmetic changes, and were not functionally altered at study completion.

9. Simulated Use Testing

Five clinical endoscope sets comprised of flexible endoscopes, procedural endoscope accessories (i.e. valves), and cleaning accessories were challenged with *Mycobacterium terrae* ATCC 15755 under worst-case temperatures (18-19°C), and organic (5% serum, final v/v), and inorganic (400 ppm AOAC hard water) conditions. A ≥ 6 $\log_{10}$ reduction of test organism was achieved for all of the endoscope sets after 8 minutes of contact with Resert XL HLD test solution, formulated to below the minimum manufacturing specification for hydrogen peroxide and stressed to the end of its reuse life.

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10. In Use testing

Pre-cleaned, representative patient soiled endoscopes were manually reprocessed in Resert XL HLD for 8 minutes at ≥ 20°C, and shown to be effectively high level disinfected under In Use test conditions.

11. Resert XL HLD Stability

Resert XL HLD will have at least a 1 year shelf life or real time test data to support claimed expiry.

12. Conclusion

The above nonclinical and device /material compatibility studies demonstrate that Resert XL HLD High Level Disinfectant is as safe and effective as the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

Mr. John R. Jack Scoville, Jr.
Fellow, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K080420
Trade/Device Name: Resert™ XL HLD High Level Disinfectant
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants/ High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: August 26, 2008
Received: August 27, 2008

Dear Mr. Scoville:

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.

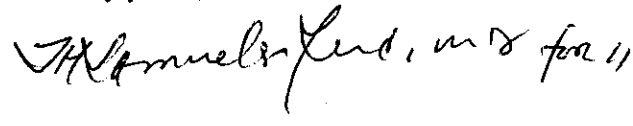
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080420

Device Name: **Resert™ XL HLD High Level Disinfectant**

Indications for Use:

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High Level Disinfectant: Resert™ XL HLD High Level Disinfectant is a high level disinfectant when used or reused undiluted for a maximum of 21 days at a minimum temperature of 20°C (68°F) for a minimum immersion time of 8 minutes.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___x___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A Murphy -S

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080420