K091022

STERIS®

APR 12 2010

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

STERIS Corporation
5960 Heisley Road
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Senior Director, Regulatory Affairs
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Summary Date: April 8, 2010

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
Contact Information:	Robert Sullivan, Sr Director Regulatory Affairs STERIS Corporation 5960 Heisley Rd ▪ Mentor OH ▪ 44060

2. Predicate Devices

Resert™ XL HLD High Level Disinfectant (K080420), manufactured by STERIS Corporation.

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

The Resert XL HLD High Level Disinfectant is identical to the predicate cleared as K080420. The statement **"It is not recommended to reprocess instruments for longer than 8 minutes."** was removed from labeling. No other changes were made to the predicate product or its labeling. The purpose of this submission is solely to obtain clearance on this revised labeling. The proposed labeling changes do not raise any new concerns of safety and effectiveness when compared to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Marcia Benedict
Director, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

APR 12 2010

Re: K091022
Trade/Device Name: Rester XL HLD High Level Disinfectant
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants / High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: March 4, 2010
Received: March 8, 2010

Dear Ms. Benedict:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

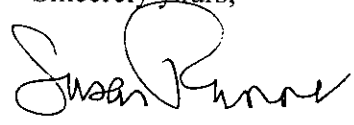
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony Watson, B.S., M.S., M.B.A.
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): **K091022**

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

Indications For Use:

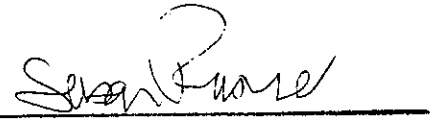
Resert™ XL HLD is a ready –to-use liquid chemical germicide. The product is a 2.0% nominal hydrogen peroxide solution. The minimum recommended concentration (MRC) is 1.5%. Resert XL HLD is intended to be used by health care practitioners in clinical settings as a ready to use liquid chemical disinfectant 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.

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



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

510(k) Number: K091022