STERIS®

[redacted]

AUG 22 2008

510(k) Summary
For
STERIS Resert XL Test Strip

STERIS Corporation
5960 Heisley Road
Mentor
OH 44060-1834

Contact: John Robert (Jack) Scoville
Fellow
Regulatory Affairs
Telephone: (440) 392-7330
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Summary Date: August 08, 2008

1. Device Name

Trade Name:	STERIS Resert XL Test Strip
Common/Usual Name:	Resert XL Test Strip
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Devices

- K972035 – SPOROX™ Test Strips
- K012335 – Browne Metrex 1.8% Glutaraldehyde Indicator

3. Description of Device

The STERIS Resert XL Test Strip is a chemical indicator strip consisting of an absorbent paper pad impregnated with the reactive chemicals, which is adhesively bonded to one end of a polymer film. The STERIS Resert XL Test Strip has been developed to monitor the Resert® XL HLD High-Level Disinfectant (K080420) that has an MRC of 1.5%.

4. Intended Use

The STERIS Resert XL Test Strip is a high level disinfectant concentration monitor dedicated for use with Resert® XL HLD High-Level Disinfectant. The purpose of the STERIS Resert XL Test Strip is to determine whether the concentration of a Resert® XL HLD High-Level Disinfectant solution is above the minimum recommended concentration (MRC) of 1.5%.

The STERIS Resert XL Test Strip only indicates hydrogen peroxide concentration and does not confirm disinfection.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicators used to monitor either hydrogen peroxide or glutaraldehyde concentration in specific solutions. The differences between the proposed STERIS Resert XL Test Strip and predicate devices are limited to differences in the device design, materials and concentration range being monitored. These differences do not raise any new issues of safety and efficacy.

A summary of the technological characteristics of the new device in comparison to those of the predicate devices is provided in Section 12 of this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 22 2008

Re: K081600
Trade/Device Name: STERIS Resert XL Test Strip
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 6, 2008
Received: June 6, 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): K081600

Device Name: STERIS Resert XL Test Strip

Indications for Use:

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The STERIS Resert XL Test Strip only indicates hydrogen peroxide concentration and does not confirm disinfection.

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)

Shula A Murphy

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

510(k) Number: K081600