FEB 9 2011

K102296

510(k) Summary
For
Verify® Chemical Monitoring Strip for Resert Solution
Version 2

STERIS Corporation
5960 Heisley Road
Mentor
OH 44060-1834

Contact: Robert Sullivan
Senior Director
Regulatory Affairs
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Summary Date: November 5, 2010

K102296

1. Device Name

Trade Name:	Verify® Chemical Monitoring Strip for Resert™ Solutions Version 2
Common/usual Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Device

- K081600 Verify Chemical Monitoring Strip for Resert Solution (cleared as STERIS Resert XL Test Strip)

3. Description of Device

The Verify Chemical Monitoring Strip for Resert Solutions Version 2 is a chemical indicator strip consisting of an absorbent paper pad impregnated with the reactive chemicals that is adhesively bonded to one end of a polymer film. The Verify Chemical Monitoring Strip for Resert Solutions Version 2 has been developed to monitor the Resert™ XL HLD High-Level Disinfectant that has a minimum recommended concentration (MRC) of 1.5%.

4. Intended Use

The Verify Chemical Monitoring Strip for Resert Solutions Version 2 is a high level disinfectant concentration monitor dedicated for use with Resert XL HLD High-Level Disinfectant. The purpose of the Verify Chemical Monitoring Strip for Resert Solution Version 2 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 Verify Chemical Monitoring Strip for Resert Solutions Version 2 only indicates hydrogen peroxide concentration and does not confirm disinfection.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are both single use chemical indicators used to monitor the hydrogen peroxide concentration in Resert XL HLD solutions. The difference between the proposed and predicate devices is limited to the relative concentrations of components in the formulation, and statements in the Instructions for Use that clarify the device's effective ambient use temperature range of 20 – 24°C. These differences raise no new issues of safety and effectiveness.

The following table summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the Verify Chemical Monitoring Strip for Resert Solutions Version 2 is safe and effective. These studies confirm that .the device's performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Test of 3 Lots	Acceptance Criteria @ 20° and 24°C		Result
	FAIL @ 1.5%	PASS @ 1.8%	
Performance Testing	100%	≥ 50%	**Pass**
Blind Study Testing	100%	≥ 50%	**Pass**
Simulated Use (Contaminants) Testing	100%	≥ 50%	**Pass**
Test Strip Life Outside the Bottle	100%	≥ 50%	**Pass**
Aggressive Chemical Stability Testing	100%	≥ 50%	**Pass**
Specificity Testing for hydrogen peroxide	100%	≥ 50%	**Pass**
Stability Testing in three storage environments through labeled shelf life	100%	≥ 50%	**Pass**
In-Use Stability Testing in three storage environments through labeled opened bottle shelf life	100%	≥ 50%	**Pass**

The Verify Chemical Monitoring Strip for Resert Solutions Version 2 is substantially equivalent to its 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

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Mr. Robert Sullivan
Senior Director
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K102296
Trade/Device Name: Verify® Chemical Monitoring Strip for Resert Solutions
Version 2
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 1, 2011
Received: February 2, 2011

Dear Mr. Sullivan:

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 D. 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): **K102296**

Device Name: Verify® Chemical Monitoring Strip for Resert Solutions Version 2

Indications for Use:

The Verify® Chemical Monitoring Strip for Resert Solutions Version 2 is a high level disinfectant concentration monitor dedicated for use with Resert® XL HLD High-Level Disinfectant. The purpose of the Verify® Chemical Monitoring Strip for Resert Solutions Version 2 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%.

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)

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

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