K102217 p.184

STERIS®

NOV 22 2010

510(k) Summary
For
Verify® SYSTEM 1E Chemical Indicator

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Contact: Robert F. Sullivan
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Submission Date: November 17, 2010

1. Device Name

Trade Name: Verify® SYSTEM 1E Chemical Indicator

Models: N/A

Common Name: Chemical Indicator

Classification Name: Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ)

2. Predicate Devices

Verify Chemical Monitoring Strip for Resert Solutions (K081600) cleared as Resert XL Test Strip

Reliance CI Process Indicator (K063285)

3. Device Description

The Verify® SYSTEM 1E Chemical Indicator is a single-use chemical indicator consisting of a polymeric strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant-permeable laminate to protect the strip from damage during handling and prevents the indicator ink from leaching from the substrate. The indicator was developed to monitor the peracetic acid (PAA) concentration of the STERIS S40 Sterilant Concentrate at the point of use in a SYSTEM 1E Liquid Chemical Sterilant Processing System during a processing cycle.

4. Intended Use:

The Verify® SYSTEM 1E Chemical Indicator (SYSTEM 1E Chemical Indicator) is a peracetic acid concentration indicator for routine monitoring of the SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate.

The unprocessed Verify® SYSTEM 1E Chemical Indicator is blue. When exposed to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution, the indicator changes color from blue through an intermediate beige and then to the endpoint color pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 use dilution.

5. Description of Safety and Substantial Equivalence

The proposed device and the Reliance CI Process Indicator predicate device both consist of a printed indicator spot on an inert polymeric substrate. The Resert XL Test Strip predicate device consists of a paper pad impregnated with indicator ink attached to an inert polymeric substrate. The active ingredients of the inks used for the proposed and predicate devices are dyes/salts that change color upon oxidation by the active (peracetic acid or hydrogen peroxide).

The proposed device, like the predicates, indicates exposure to a targeted effective concentration or dose of active by a color change to the designated end point. The proposed device changes from blue to pink when exposed to concentrations of peracetic acid greater than 1820 ppm; the predicate devices also each indicate exposure to the effective concentration or dose of the active germicide by a color change as described in their respective labeling.

Therefore, the differences between the proposed and predicate oxidative chemistry concentration monitors are limited to differences in the indicator ink composition, in the active being detected and device materials (for one predicate device) and/or the concentration range being monitored. These differences in technological characteristics do not raise any new issues of safety and effectiveness.

6. Performance Testing

Performance testing was conducted to determine that the Verify® SYSTEM 1E Chemical Indicator is an effective monitor for the peracetic acid concentration of the use dilution of the SYSTEM 1E Liquid Chemical Sterilant Processing Cycle.

The following table summarizes the non-clinical testing performed to demonstrate that the Verify® SYSTEM 1E Chemical Indicator is safe and effective. The performance testing has demonstrated that the Verify SYSTEM 1E Chemical Indicator is substantially equivalent to its predicates and raises no new questions of safety or effectiveness.

Testing	Results
Comparative Sensitivity and Specificity	***PASS*** The Verify SYSTEM 1E Chemical Indicator can correctly identify PASS or FAIL conditions for PAA concentrations in the SYSTEM 1E Liquid Chemical Sterilant Processing System.
Color Read Time	***PASS*** The observed color of Verify SYSTEM 1E Chemical Indicators has been shown to be stable for 30 minutes following completion of the processor cycle. However, it is recommended that the PASS/FAIL evaluation be made immediately after the CI strip is removed from the processor.
Analytic Specificity	***PASS*** Under conditions of normal storage and use, as indicated in the labeling, any color change observed in a processed Verify SYSTEM 1E Chemical Indicator will be the result of the presence of PAA in the processor use dilution.
Blind Reader	***PASS*** Blind Readers correctly evaluated 179 of 179 randomly displayed processed Verify SYSTEM 1E Chemical Indicators.
Simulated Use Testing	***PASS*** The addition of a medical device to the processing chamber does not affect the performance of the Verify SYSTEM 1E Chemical Indicator.
UV Study	***PASS*** The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicators protects the unprocessed strips from the effects of UV light.
Shelf Life	***PASS*** The Verify SYSTEM 1E Chemical Indicator maintains appropriate indicator characteristics after 15 months of storage.
Effects of Aggressive Chemicals	***PASS*** The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicator protects the unprocessed strips from the effects of aggressive chemicals.
Effects of Contaminants	***PASS*** The presence of possible contaminants from inadequate cleaning or rinsing of the medical devices does not affect the expected color change of processed Verify SYSTEM 1E Chemical Indicators.
Open Bottle Stability	***PASS*** At the 13 month time point, The Verify SYSTEM 1E Chemical Indicators demonstrated the appropriate FAIL results.

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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NOV 2 2 2010

Re: K102217
Trade/Device Name: Verify® SYSTEM 1E Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 17, 2010
Received: November 18, 2010

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.

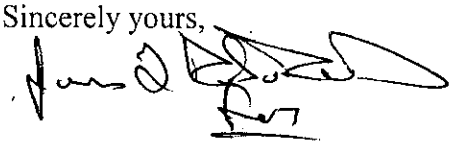
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.M., M.B.A.
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Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

K102217

Indications for Use

510(k) Number (if known):

NOV 2 2 2010

Device Name: **Verify® SYSTEM 1E Chemical Indicator**

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The Verify® SYSTEM 1E Chemical Indicator (SYSTEM 1E Chemical Indicator) is a peracetic acid concentration indicator for routine monitoring of the SYSTEM1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate. The unprocessed Verify® SYSTEM 1E Chemical Indicator is blue. When exposed to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution, the indicator changes color from blue through an intermediate beige and then to the endpoint color pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 use dilution.

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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