

STERIS®



NOV 22 2010

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

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
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Contact: Robert F. Sullivan
Senior Director,
FDA Regulatory Affairs
Telephone: (440) 392-7695
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Submission Date: November 17, 2010

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

November 17, 2010

Appendix B: Page 2 of 5

**K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator**

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.

**K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator**

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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.

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**K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator**

Testing	Results
Comparative Sensitivity and Specificity	<p align="center">PASS</p> <p>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.</p>
Color Read Time	<p align="center">PASS</p> <p>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.</p>
Analytic Specificity	<p align="center">PASS</p> <p>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.</p>
Blind Reader	<p align="center">PASS</p> <p>Blind Readers correctly evaluated 179 of 179 randomly displayed processed Verify SYSTEM 1E Chemical Indicators.</p>
Simulated Use Testing	<p align="center">PASS</p> <p>The addition of a medical device to the processing chamber does not affect the performance of the Verify SYSTEM 1E Chemical Indicator.</p>
UV Study	<p align="center">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicators protects the unprocessed strips from the effects of UV light.</p>
Shelf Life	<p align="center">PASS</p> <p>The Verify SYSTEM 1E Chemical Indicator maintains appropriate indicator characteristics after 15 months of storage.</p>
Effects of Aggressive Chemicals	<p align="center">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicator protects the unprocessed strips from the effects of aggressive chemicals.</p>
Effects of Contaminants	<p align="center">PASS</p> <p>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.</p>
Open Bottle Stability	<p align="center">PASS</p> <p>At the 13 month time point, The Verify SYSTEM 1E Chemical Indicators demonstrated the appropriate FAIL results.</p>



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

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

NOV 22 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.

Page 2- Mr.Sullivan

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

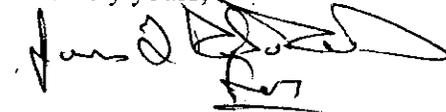
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding 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.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102217

Indications for Use

510(k) Number (if known):

NOV 22 2010

Device Name: Verify® SYSTEM 1E Chemical Indicator

Indications For Use:

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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

Page 1 of 1

510(k) Number: K102217



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

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

NOV 22 2010

Re: K102217

Trade/Device Name: Verify[®] SYSTEM 1E Chemical Indicator
Regulation Number: 21 CFR 880.2800
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Anthony D. Watson, B.S., M.M., 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

K102217

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AND/OR

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Page 1 of 1

510(k) Number: K102217

August 5, 2010

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 19, 2010

STERIS CORPORATION
5960 HEISLEY ROAD
MENTOR, OHIO 44060
UNITED STATES
ATTN: ROBERT F. SULLIVAN

510k Number: K102217

Product: SYSTEM 1E CHEMICAL INDICATOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 18, 2010

STERIS CORPORATION
5960 HEISLEY ROAD
MENTOR, OHIO 44060
UNITED STATES
ATTN: ROBERT F. SULLIVAN

510k Number: K102217

Product: SYSTEM 1E CHEMICAL INDICATOR

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records released under FOIA Request #7019905. Released by CDRH on 06/06/2016.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 13, 2010

STERIS CORPORATION
5960 HEISLEY ROAD
MENTOR, OHIO 44060
UNITED STATES
ATTN: ROBERT F. SULLIVAN

510k Number: K102217

Product: SYSTEM 1E CHEMICAL INDICATOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

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Sincerely,

510(k) Staff



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 10, 2010

STERIS CORPORATION
5960 HEISLEY ROAD
MENTOR, OHIO 44060
UNITED STATES
ATTN: ROBERT F. SULLIVAN

510k Number: K102217

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Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

40



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 07, 2010

STERIS CORPORATION
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ATTN: ROBERT F. SULLIVAN

510k Number: K102217

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Sincerely,

510(k) Staff

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10903 New Hampshire Avenue
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August 27, 2010

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510k Number: K102217

Product: SYSTEM 1E CHEMICAL INDICATOR

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ◊ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 06, 2010

STERIS CORPORATION
5960 HEISLEY RD.
MENTOR, OHIO 44060
UNITED STATES
ATTN: ROBERT F. SULLIVAN

510k Number: K102217

Received: 8/6/2010

Product: SYSTEM 1E CHEMICAL INDICATOR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

STERIS®



August 5, 2010

K102217

U.S. Food and Drug Administration,
Center for Devices and Radiological Health,
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

AUG 06 2010

Received

RE: *TRADITIONAL 510(k) PREMARKET NOTIFICATION*
Verify® SYSTEM 1E Chemical Indicator
Medical Device User Fee Payment ID Number: MD6050483-956733

1<-38

Dear Sir/Madam:

Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of a Traditional 510(k) for the Verify® SYSTEM 1E Chemical Indicator. The proposed Verify® SYSTEM 1E Chemical Indicator is a process indicator developed and validated specifically for use in the SYSTEM 1E Liquid Chemical Sterilization System, submitted for clearance as K090036.

Physical/chemical sterilization process indicators are classified as Class II devices (Product Code JOJ) per 21 CFR 880.2800 and are reviewed by the General Hospital and Personal Use Devices Panel.

The principal factors of the design and use of the Verify® SYSTEM 1E Chemical Indicator are listed below in tabular format.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Office of Device Evaluation
August 5, 2010
Page 2 of 2

This Premarket Notification is submitted in accordance with 21 CFR 807, Subpart E and FDA Guidance "Guidance for Industry and FDA Staff; Premarket Notification [510(k)] Submissions for Chemical Indicators" dated December 19, 2003. "Guidance for Industry and FDA Staff; Format for Traditional and Abbreviated 510(k)s" dated August 12, 2005, was used for formatting of this submission. All sections, whether applicable or not, are included as recommended in this guidance. A Table of Contents and the optional Screening Checklist are included as part of section 003 following this letter.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification.

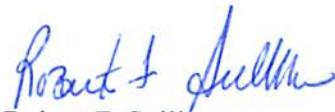
In accordance with MDUFMA, STERIS Corporation has sent the required User Fee of \$4,007. A copy of the Medical Device User Fee Cover Sheet is provided as the first section of this submission.

All correspondence concerning this submission should be directed to:

Robert F. Sullivan
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert.Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,



Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
--	---

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) STERIS CORP 5960 HEISLEY RD MENTOR OH 44060 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2024	2. CONTACT NAME Robert Sullivan 2.1 E-MAIL ADDRESS robert_sullivan@steris.com 2.2 TELEPHONE NUMBER (include Area code) 440-392-7695 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 440-357-9198
---	--

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select a center
<input type="checkbox"/> 513(g) Request for Information	<input checked="" type="checkbox"/> CDRH
<input type="checkbox"/> Biologics License Application (BLA)	<input type="checkbox"/> CBER
<input type="checkbox"/> Premarket Approval Application (PMA)	3.2 Select one of the types below
<input type="checkbox"/> Modular PMA	<input checked="" type="checkbox"/> Original Application
<input type="checkbox"/> Product Development Protocol (PDP)	Supplement Types:
<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> Efficacy (BLA)
<input type="checkbox"/> Annual Fee for Periodic Reporting (APR)	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)
<input type="checkbox"/> 30-Day Notice	<input type="checkbox"/> Real-Time (PMA, PMR, PDP)
	<input type="checkbox"/> 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) *Robert J Sullivan* 14-Jul-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 8/5/2010	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	<input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name STERIS Corporation		Establishment Registration Number (if known) 1527821	
Division Name (if applicable)		Phone Number (including area code) (440) 392-7695	
Street Address 5960 Heisley Rd		FAX Number (including area code) (440) 357-9198	
City Mentor	State / Province OH	ZIP/Postal Code 44060	Country USA
Contact Name Robert F Sullivan			
Contact Title Senior Director, FDA Regulatory Affairs		Contact E-mail Address RSullivan@STERIS.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION E ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement			
1	JOJ	2				3	
5		6				7	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K052535	1	Verify SPI Chemical Indicator	1	Albert Browne (STERIS Corporation)
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Physical / Chemical Sterilization Process Indicator

	Trade or Proprietary or Model Name for This Device		Model Number
1	SYSTEM 1E Chemical Indicator	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
K092865					
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code JOJ	C.F.R. Section (if applicable) 21 CFR 880.2800	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel GENERAL HOSPITAL AND PERSONAL USE DEVICES		

Indications (from labeling)
 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 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.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1527821		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name STERIS Corporation			Establishment Registration Number 8021896		
Division Name (if applicable) Albert Browne Ltd.			Phone Number (including area code) (011) 44 116 2768636		
Street Address Chancery House 190 Waterside Road Hamilton Industrial Park			FAX Number (including area code) (011) 44 116 2768639		
City Leicester		State / Province	ZIP/Postal Code LE5 1QZ	Country United Kingdom	
Contact Name Richard Bancroft		Contact Title Development and Technical Service Director		Contact E-mail Address Richard_Bancroft@STERIS.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control



August 5, 2010

U.S. Food and Drug Administration,
 Center for Devices and Radiological Health,
 Document Mail Center – WO66-0609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

RE: TRADITIONAL 510(k) PREMARKET NOTIFICATION
Verify® SYSTEM 1E Chemical Indicator
Medical Device User Fee Payment ID Number: MD6050483-956733

Dear Sir/Madam:

Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of a Traditional 510(k) for the Verify® SYSTEM 1E Chemical Indicator. The proposed Verify® SYSTEM 1E Chemical Indicator is a process indicator developed and validated specifically for use in the SYSTEM 1E Liquid Chemical Sterilization System, submitted for clearance as K090036.

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The principal factors of the design and use of the Verify® SYSTEM 1E Chemical Indicator are listed below in tabular format.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Office of Device Evaluation

August 5, 2010

Page 2 of 2

This Premarket Notification is submitted in accordance with 21 CFR 807, Subpart E and FDA Guidance "Guidance for Industry and FDA Staff; Premarket Notification [510(k)] Submissions for Chemical Indicators" dated December 19, 2003. "Guidance for Industry and FDA Staff; Format for Traditional and Abbreviated 510(k)s" dated August 12, 2005, was used for formatting of this submission. All sections, whether applicable or not, are included as recommended in this guidance. A Table of Contents and the optional Screening Checklist are included as part of section 003 following this letter.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification.

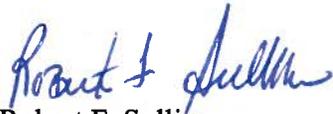
In accordance with MDUFMA, STERIS Corporation has sent the required User Fee of \$4,007. A copy of the Medical Device User Fee Cover Sheet is provided as the first section of this submission.

All correspondence concerning this submission should be directed to:

Robert F. Sullivan
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert.Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,



Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

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STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on
Guidance for Industry and FDA Staff
[Format for Traditional and Abbreviated 510\(k\)s](#)

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	Section 001		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet	Section 002		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Section 003		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	Section 004		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E	Section 005		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	Section 006		
Class III Summary and Certification	Class III Summary and Certification Form			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators			X
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity	Section 009		

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

	Required Elements for Declaration of Conformity to Recognized Standard			
Executive Summary	See section 10 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005	Section 010		
Device Description	See section 11 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005	Section 011		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	Section 012		
Proposed Labeling	Device Advice “ Content of a 510(k)” Section H	Section 013		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	Section 014		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	Section 015		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices			X
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1- 2 Medical			X

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR

	Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Section 018		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators			X
Kit Certification	Device Advice: Special Considerations			X

Page Last Updated: 06/18/2009

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Indications for Use

510(k) Number (if known):

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

Indications For Use:

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)



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

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Robert F. Sullivan
Senior Director,
FDA Regulatory Affairs
Telephone: (440) 392-7695
Fax No: (440) 357-9198

Submission Date: August 5, 2010

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
SYSTEM 1E CHEMICAL INDICATOR**

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 Device

Verify[®] Chemical Indicator for SYSTEM 1[®] Sterile Processing System (K052535), cleared as Verify SPI Chemical Indicator

3. Device Description

The Verify[®] SYSTEM 1E Chemical Indicator is a single-use chemical indicator consisting of a polypropylene 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.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
SYSTEM 1E CHEMICAL INDICATOR**

5. Description of Safety and Substantial Equivalence

The Verify SYSTEM 1E Chemical Indicator raises no new questions of safety or effectiveness and is substantially equivalent to its predicate.

6. Performance Testing

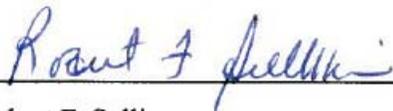
Performance testing was conducted to determine that the Verify[®] SYSTEM 1E Chemical Indicator is an effective monitor for the peracetic acid concentration of the use dilution of the SYSTEM 1E Liquid Chemical Sterilant Processing Cycle.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

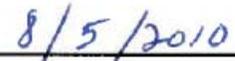
Premarket Notification

TRUTHFUL and ACCURACY STATEMENT
(As Required by 21 CFR 807.87))

Pursuant to 21 CFR 80.87(k), I, Robert F. Sullivan, certify that in my capacity as Senior Director of FDA Regulatory Affairs, believe to the best of my knowledge that all data and information submitted in the **Verify® SYSTEM 1E Chemical Indicator** Premarket Notification are truthful and accurate and no material fact has been omitted.



Robert F. Sullivan



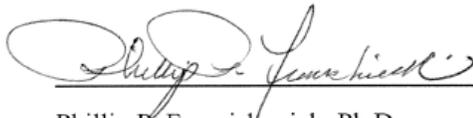
Date

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Premarket Notification

TRUTHFUL and ACCURACY STATEMENT
(As Required by 21 CFR 807.87))

Pursuant to 21 CFR 80.87(k), I, Dr. Phillip P. Franciskovich, certify that in my capacity as Director of New Products, Science and Technology (Project Sponsor), believe to the best of my knowledge that all data and information submitted in the **Verify® SYSTEM 1E Chemical Indicator** Premarket Notification are truthful and accurate and no material fact has been omitted.



Phillip P. Franciskovich, Ph.D.

August 5, 2010
Date

Class III Summary and Certification
For
Verify[®] SYSTEM 1E Chemical Indicator

This section does not apply.

Financial Certification or Disclosure Statement
For
Verify[®] SYSTEM 1E Chemical Indicator

This section does not apply.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

DECLARATION OF CONFORMITY

STERIS is not referencing or claiming conformity to standards in this submission, therefore there are no FDA 3654 forms included in this premarket submission.

Traditional 510(k) Executive Summary
For
Verify[®] SYSTEM 1E Chemical Indicator

1. Company Name and Address

1.1 Sponsor

STERIS Corporation
5960 Heisley Rd.
Mentor, Ohio 44060

Contact: Robert F. Sullivan
Senior Director
FDA Regulatory Affairs

Telephone: (440) 392-7695
Fax No: (440) 357-9198

Manufacturing Facility

Albert Browne Ltd., a subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

2. Device Name

Trade Name: Verify[®] SYSTEM 1E Chemical Indicator
Common Name: Chemical Indicator
Classification Name: Physical/chemical sterilization process indicator

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

3. Establishment Registration Number

STERIS Corporation
5960 Heisley Rd.
Mentor, Ohio 44060
Registration number: 1527821

Albert Browne Ltd., a subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
Registration number: 8021896

4. Device Classification

Class: II
Classification Number: 21 CFR 880.2800
Classification Panel: General Hospital and Personal Use Devices Panel
FDA Review Product Code: JOJ

5. Predicate Device

STERIS Verify[®] Chemical Indicator for STERIS SYSTEM 1[®] Sterile Processing System (cleared as Verify[®] SPI Chemical Indicator, K052535)

6. Overview

The purpose of this 510(k) Premarket notification is to obtain premarket clearance for the Verify[®] SYSTEM 1E Chemical Indicator for use in the SYSTEM 1E Liquid Chemical Sterilant Processing System (K090036). This Premarket notification contains additional information as requested by FDA (b)(4)

7. Device Description

The Verify[®] SYSTEM 1E Chemical Indicator is a single-use chemical indicator consisting of a polypropylene 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 prevent 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

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

SYSTEM 1E Liquid Chemical Sterilization System processor during a processing cycle.

8. 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.

9. Device Comparison Table

Table 10-1. Device Comparison Table

Feature	Proposed Verify® SYSTEM 1E Chemical Indicator	Verify® SPI Chemical Indicator (K052535)
Intended use	Process Indicator for Peracetic Acid	Process Indicator for Peracetic Acid
Device design - components	Printed indicator ink printed on to polypropylene overlaid with a clear, permeable laminate	Printed indicator ink printed on to polypropylene overlaid with a clear, permeable laminate
Indicator agent	(b)(4)	
Sterilization method and cycles	SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate	STERIS SYSTEM 1® Sterile Processing System employing STERIS S20 Sterilant Concentrate
Mechanism of action	(b)(4)	
Peracetic Acid (PAA) Concentration Required for an Endpoint Color Change	≥ 1820 mg/L PAA	≥ 1800 mg/L PAA

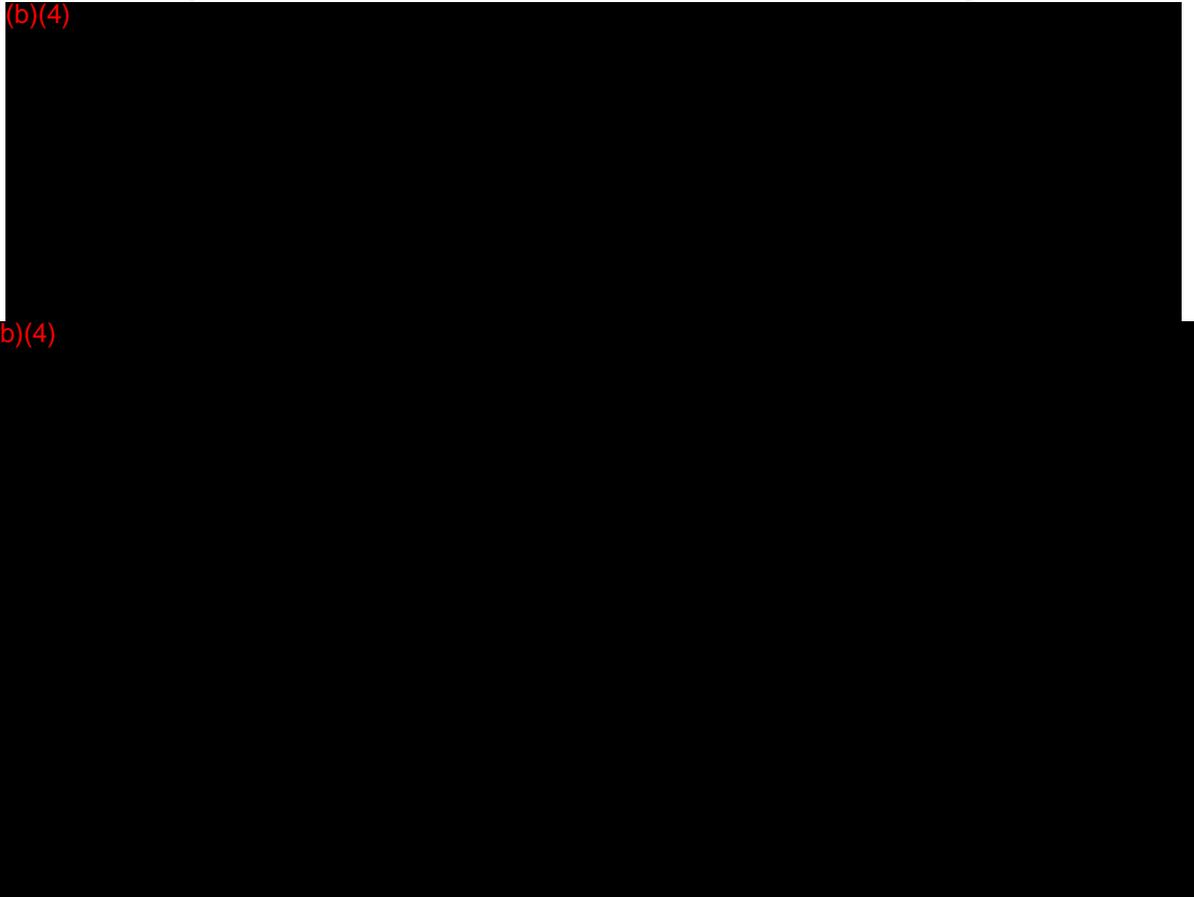
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
 VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Feature	Proposed Verify® SYSTEM 1E Chemical Indicator	Verify® SPI Chemical Indicator (K052535)
Disposable	Yes	Yes
Shelf-life	2 years (proposed)	1 year

10. Performance Testing Summary

The proposed Verify® System 1E Chemical Indicator was tested to demonstrate compliance with performance requirements for the SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate. **This Executive Summary and Section 18 - Performance Testing –Bench** of this Premarket Submission, contain detailed information regarding the proposed Verify® System 1E Chemical Indicator Performance Testing.

All tests were performed as described in Verification of the Chemical Indicator for use in the STERIS SYSTEM 1E Liquid Chemical Sterilant Processor (10028753) Protocol (**Appendix A**). For each study, three (3) production lots of the proposed Verify® System 1E Chemical Indicator were utilized. These lots are identified in **Table 10-2** below. The SYSTEM 1E Chemical Sterilant Processing System was used in conjunction with S40 Sterilant Concentrate containers with the specified



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Processed strips were classified as PASS or FAIL in accordance with the following criteria:

A **PASS** is as pink or more pink than the PASS Reference Color Block.

A **FAIL** is less pink than the PASS Reference Color Block.

The bench testing performed is summarized below and in the Master Report (10028889, provided as **Appendix B** of this submission). Each test is detailed in **Section 18: Performance Testing – Bench** and in the respective reports provided as Appendices as outlined in **Table 10.3**.

Table 10-3. Verify® System 1E Chemical Indicator Testing Summary

Testing	Report Number(s)	Appendix
Comparative Sensitivity and Specificity	10028892	C
Color Read Time if Removal from the Processor is Delayed	10028893	D
Color Read Time Immediately After The Processor Cycle	10028894	E
Analytic Specificity	10028865	F
Blind Reader	10028753	G
Simulated Use Testing	10028897	H
UV Study	11028898	I
Shelf Life	10028999	J
Effects of Aggressive Chemicals	11028900	K
Effects of Contaminants	10028901	L
Open Bottle Stability	RDP.154SSL4, 5 & 6	M
Toxicity Analysis	N/A	N

10.1 Performance Testing

Comparative Sensitivity and Specificity

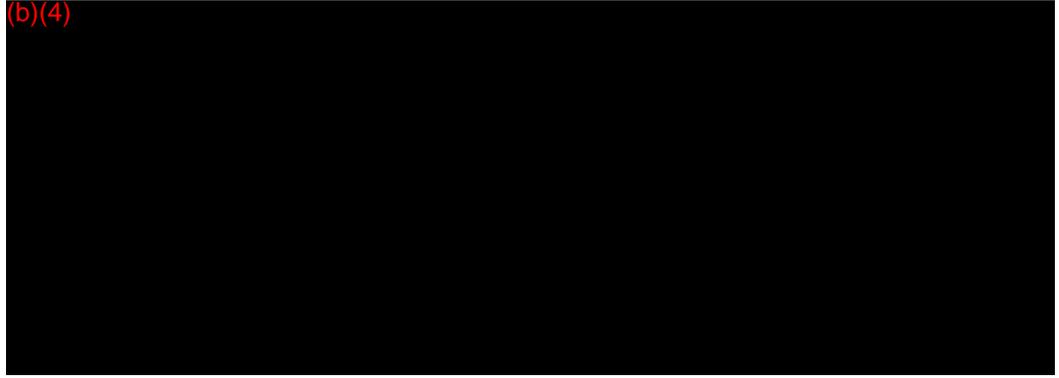
The final report describing the performance testing for comparative sensitivity and specificity of the Verify® System 1E Chemical Indicator is provided in **Appendix C** of this submission.

Testing of the Verify® SYSTEM 1E Chemical Indicator (CI) was conducted in the SYSTEM 1E™ Processor using S40™ Sterilant Concentrate at two targeted concentrations. The outcomes were read using Reference color

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

squares. All results passed the acceptance criteria set forth in the Verification of the Chemical Indicator for use in the STERIS SYSTEM 1E Liquid Chemical Sterilant Processor Protocol (**Appendix A**) and the

(b)(4)



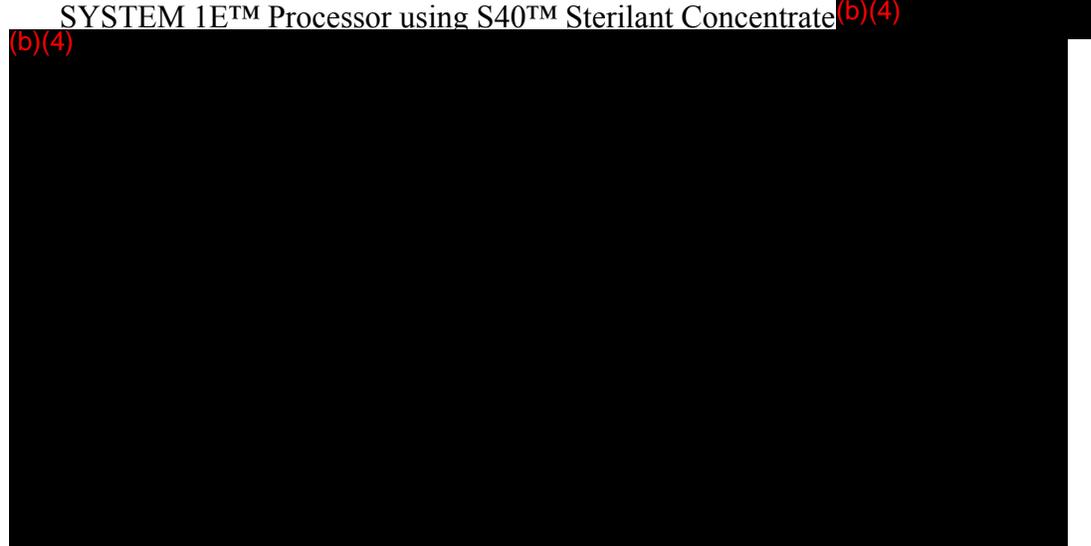
Comparative Sensitivity and Specificity values of 1.00 demonstrated the ability of the processed Verify® System 1E Chemical Indicator strip to provide reliable results for processed strips exposed to PAA concentrations at or just below the MRC concentration.

Color Read Time Immediately After The Processor Cycle

The final report describing the performance testing for when the color read of the Verify® System 1E Chemical Indicator is taken immediately after the processor cycle is provided in **Appendix D** of this submission.

Testing of the SYSTEM 1E Chemical Indicator (CI) was conducted in the SYSTEM 1E™ Processor using S40™ Sterilant Concentrate (b)(4)

(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

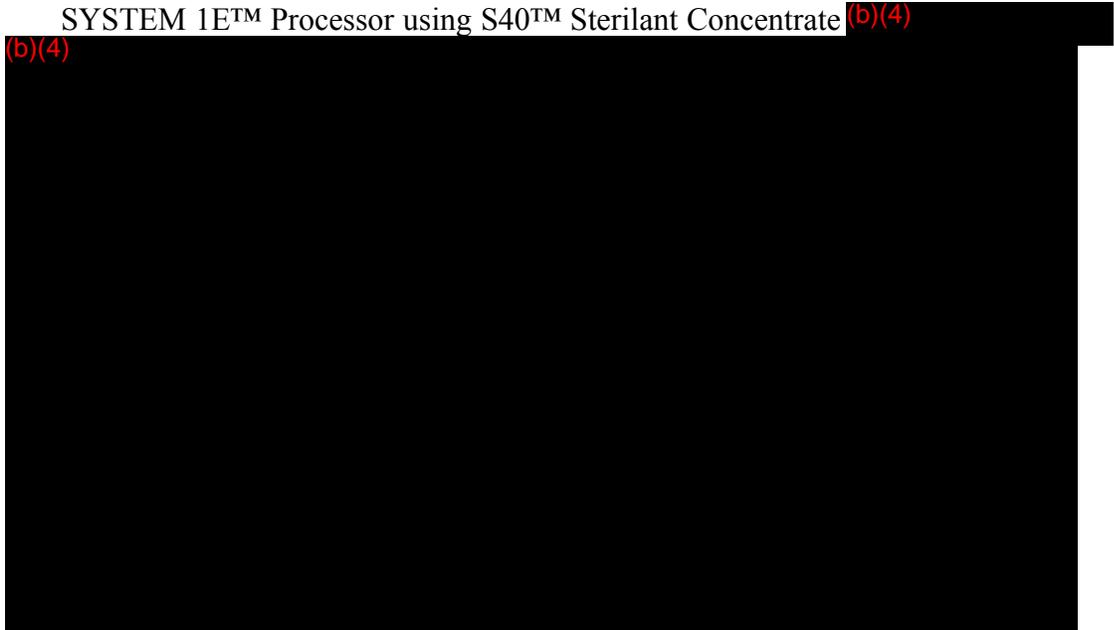
The Verify[®] System 1E Chemical Indicator strips show accurate evaluation outcomes in all cases when read 30 minutes after removal from the processor. However, *it is recommended that after completion of the cycle the processed Verify[®] System 1E Chemical Indicator strips be read immediately.*

Color Read Time If Removal From The Processor Is Delayed

The final report describing the performance testing for when the color evaluation of the Verify[®] System 1E Chemical Indicator is delayed after the processor cycle has been completed and the processor lid is opened, is provided in **Appendix E** of this submission.

Testing of the Verify[®] System 1E Chemical Indicator was conducted in the SYSTEM 1E[™] Processor using S40[™] Sterilant Concentrate (b)(4)

(b)(4)

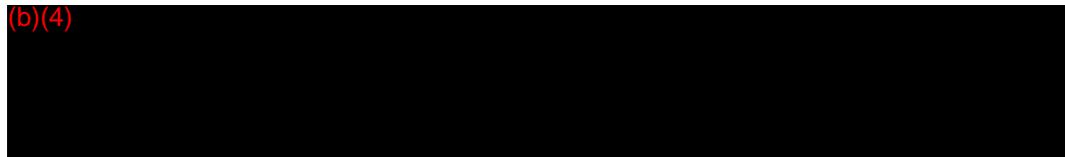


The strips show accurate evaluation results in all cases when removed from the processor and evaluated 30 minutes after completion of the cycle. However, *it is recommended that the processed Verify[®] System 1E Chemical Indicator strips be evaluated immediately after completion of the cycle.*

Analytic Specificity

The report detailing the analytic specificity of the Verify[®] System 1E Chemical Indicator is provided in **Appendix F** of this submission.

(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

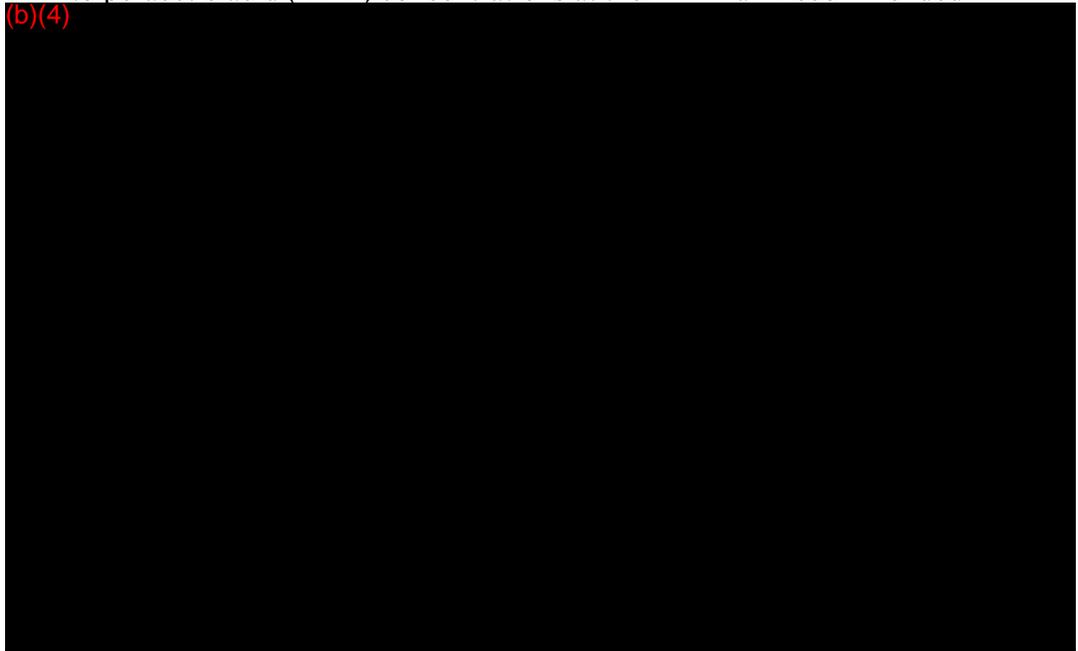
change from the START Reference color. Therefore, the Verify® System 1E Chemical Indicator strips demonstrated analytic specificity since any observable color change in a strip processed according to product labeling would be the result of exposure to the concentrated peracetic acid solution from the S40 Sterilant Concentrate, when used in the SYSTEM 1E Processor.

10.2 Blind Study Testing

The report detailing blind reader evaluation testing of the Verify® System 1E Chemical Indicator is provided in **Appendix G** of this submission.

Testing of the Verify® System 1E Chemical Indicator was conducted in the SYSTEM 1E™ Processor using S40™ Sterilant Concentrate to determine if 3 blind readers could distinguish a color difference between strips exposed to peracetic acid (PAA) concentrations at the minimum recommended

(b)(4)



The CI strips can effectively demonstrate 100% FAIL rate at or just below MRC and 100% PASS rate at a concentration above MRC as evaluated by three blinded readers.

10.3 Simulated Use Testing

The report detailing the simulated use testing of the Verify® System 1E Chemical Indicator is provided in **Appendix H** of this submission.

Under simulated use conditions (i.e. a medical device in the processor chamber of the SYSTEM 1E Processor) all chemical indicators tested passed acceptance criteria set forth in the Verification of the Chemical

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Indicator for use in the SYSTEM 1E Processor Protocol (**Appendix A**). The

(b)(4)

(b)(4)

The addition of a medical device to the processing chamber does not affect the performance of the CI strips.

10.4 Light Stability Testing

Light stability testing to verify that the proposed Verify® System 1E Chemical Indicator is not affected by exposure to light before processing is provided in **Appendix I** of this submission.

Chemical indicator (CI) strips from three production lots were used to

(b)(4)

Unprocessed strips should be kept in the shipping and storage bottle until ready for use in the SYSTEM 1E Processor so the unprocessed strips will be protected from UV light exposure and the observed color change of the processed CI strip will be reliable. Also, unprocessed strips should always be compared to the START Reference square prior to use. Any strips that do not match the START color should not be used as indicated in the device labeling.

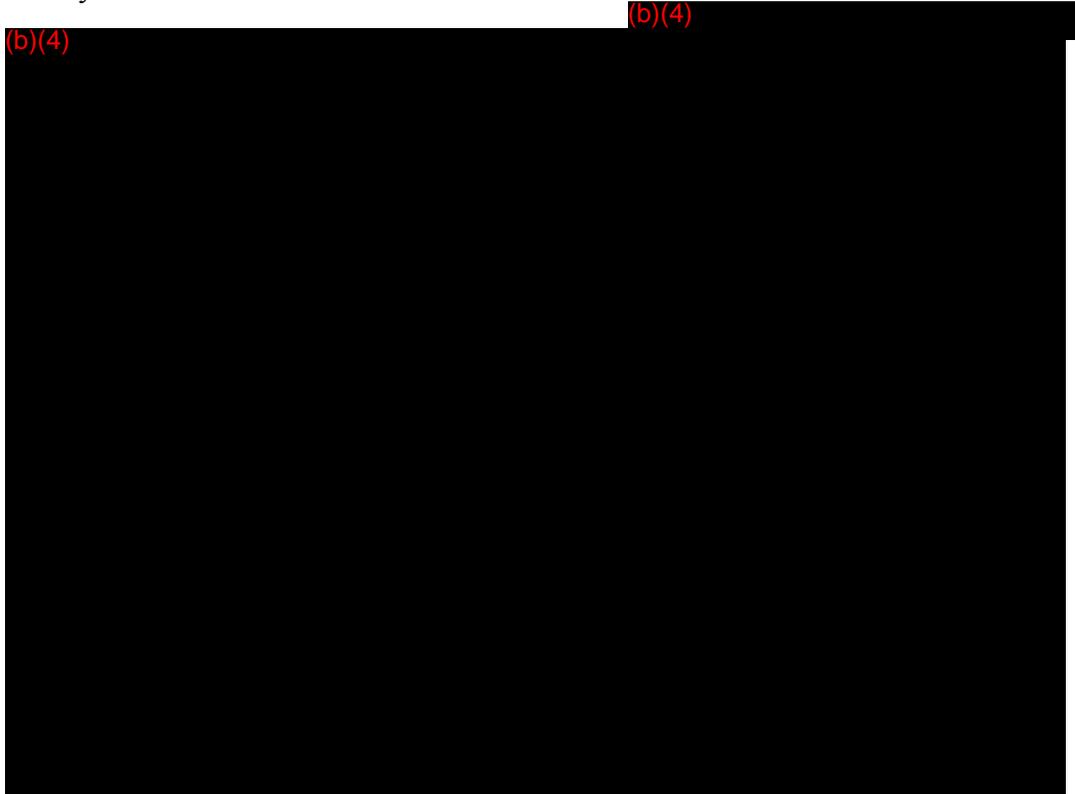
10.5 Shelf Life Testing

It is the intention of STERIS Corporation to claim a 24 month shelf life for the Verify® System 1E Chemical Indicator based on real time stability data. STERIS does not yet have an inventory of the proposed Verify® System 1E

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Chemical Indicator to support the proposed shelf life. Testing for the indicated shelf life time points will be performed in accordance with the procedures outlined in **Appendix A, Section 5.8**.

Testing to date, supporting a 15 month shelf life, is included in **Appendix J**. Until appropriate testing is completed on extended time points, **STERIS intends to claim the 15 month shelf life**. Current testing of the Verify[®] System 1E Chemical Indicator was conducted in the SYSTEM 1E[™]



All results passed the acceptance criteria set forth in the Verification of the Chemical Indicator for use in the SYSTEM 1E Processor Protocol (**Appendix A**).

Together, the test results demonstrate that *the shelf life for the bottled Verify[®] System 1E Chemical Indicator is at least 15 months*.

A promissory statement that STERIS will not make extended shelf-life claims or stability claims without having the supporting testing information is provided as **Appendix O**.

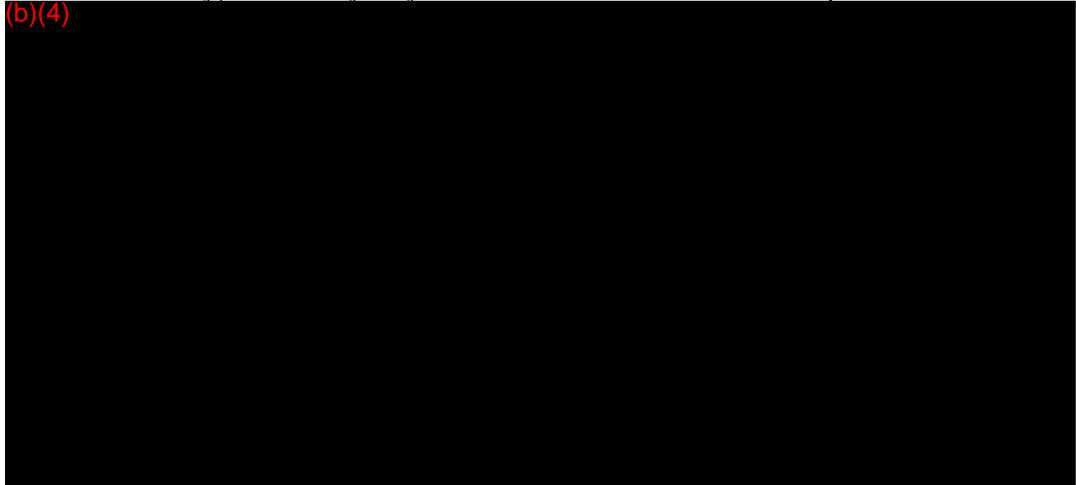
10.6 Aggressive Chemical Stability Testing

The report detailing aggressive chemical stability testing of the Verify[®] System 1E Chemical Indicator is provided in **Appendix K** of this submission.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

In this study, the Verify[®] System 1E Chemical Indicator strips from 3

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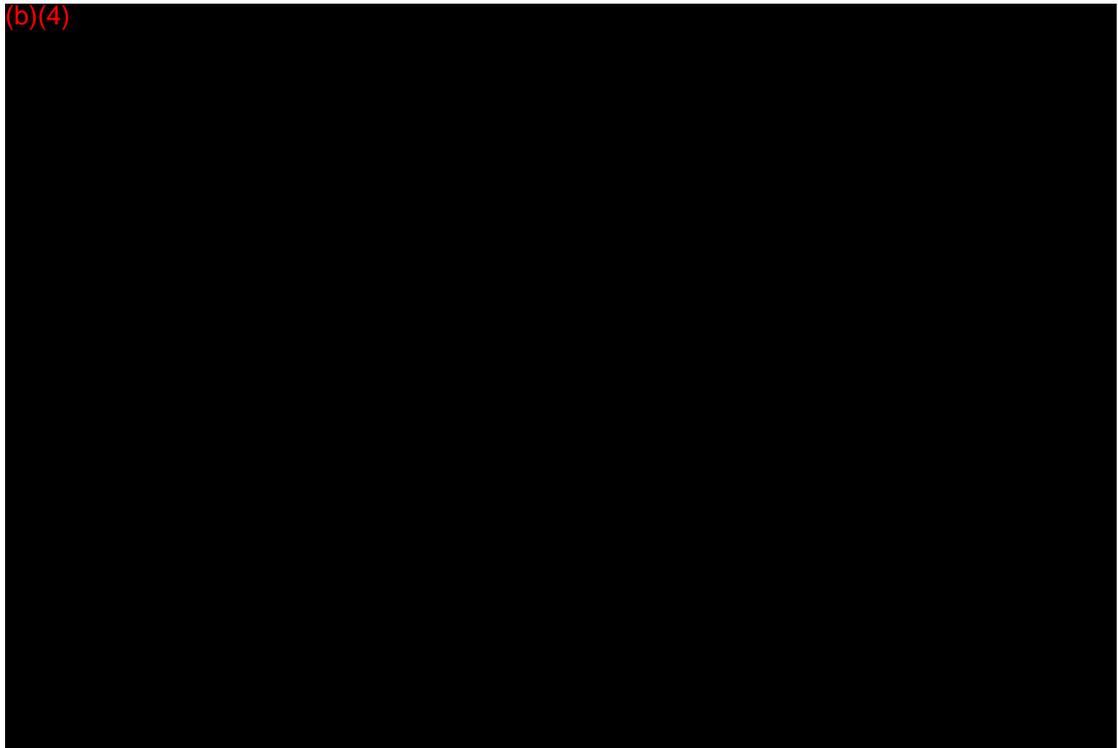


Unprocessed Verify[®] System 1E Chemical Indicator strips should be kept in the shipping and storage bottle until ready for use in the SYSTEM 1E Processor so the unprocessed strips will be protected from aggressive chemical exposure and the observed color change of the processed CI strip will be reliable.

10.7 Contaminants Testing

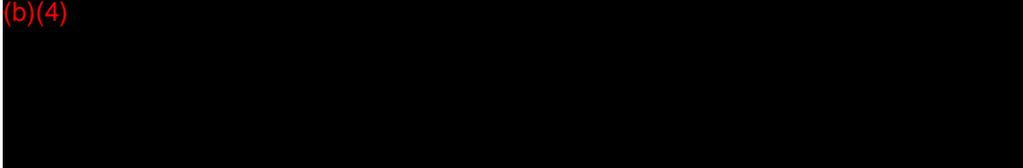
The report detailing the effects of contaminants on the Verify[®] System 1E Chemical Indicator is provided in **Appendix L** of this submission.

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

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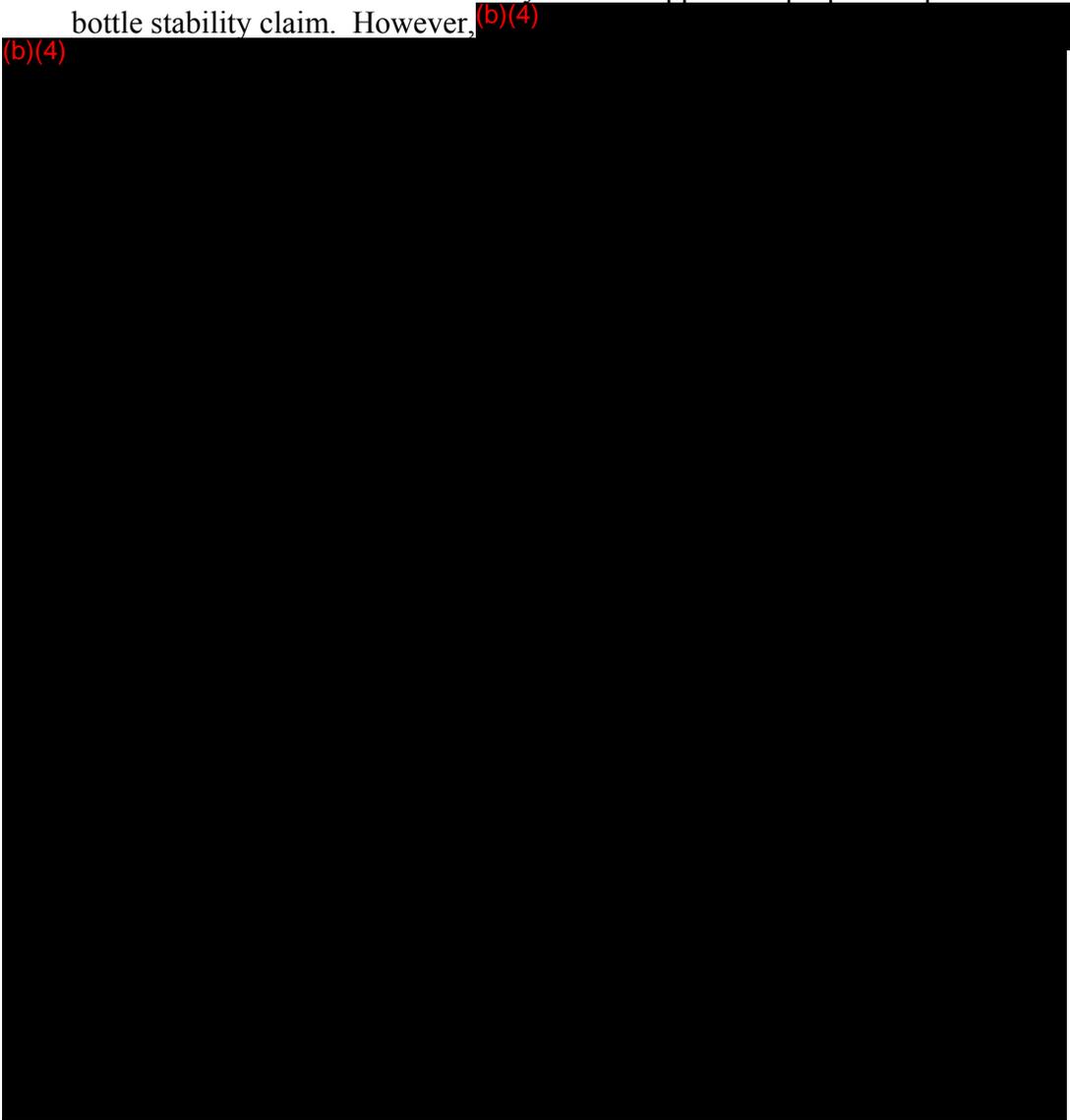


These studies demonstrated that the presence of possible contaminants from inadequate cleaning or incomplete rinsing of the medical devices does not affect the expected color change of CI strips processed in the SYSTEM 1E Processor.

10.8 Open Bottle Stability Testing

It is the intention of STERIS Corporation to claim a 6 month shelf life for the Verify® System 1E Chemical Indicator following opening of the bottle. This claim shall be based on real time stability data. STERIS does not yet have data based on the current test system to support the proposed open bottle stability claim. However, (b)(4)

(b)(4)



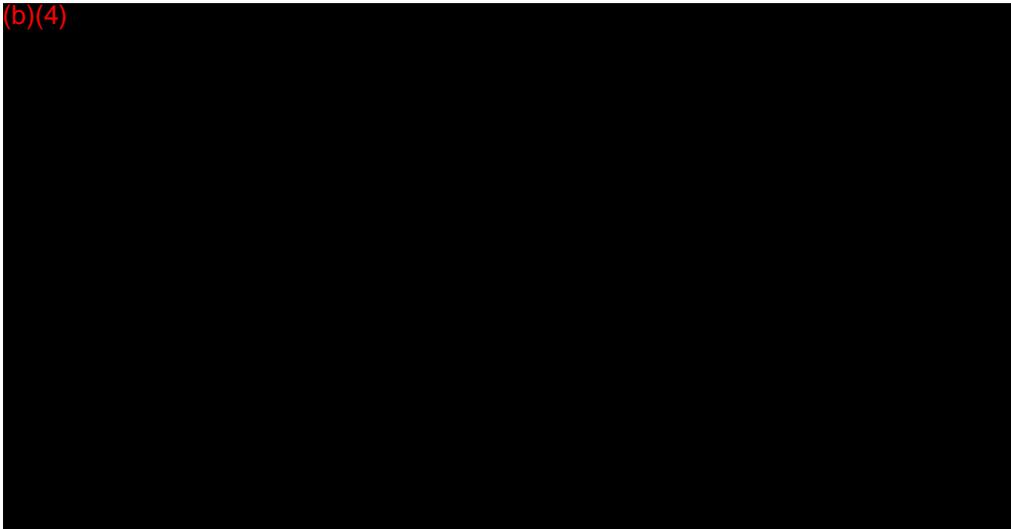
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

The results for this earlier testing are given in the study reports supplied in

(b)(4)



(b)(4)



10.9 Toxicity Analysis

The Verify[®] SYSTEM 1E Chemical Indicator does not contain components that come into direct or indirect contact with patients.

The Verify[®] SYSTEM 1E Chemical Indicator consists of reactive chemicals printed on one end of a polypropylene strip. A clear, sterilant-permeable polyether block amide laminate is adhesively bonded to the polypropylene strip following printing of the ink, completely covering the ink.

A Hazard Analysis for the proposed Verify[®] SYSTEM 1E Chemical Indicator is included in **Appendix N**.

10.10 Conclusions

Test data demonstrates that the proposed Verify[®] SYSTEM 1E Chemical Indicator meets the performance requirements and is safe and effective for use in routine monitoring of the of the SYSTEM 1E[™] Liquid Chemical Sterilant Processing System employing S40[™] Sterilant Concentrate (K090036).

Device Description

For

Verify[®] SYSTEM 1E Chemical Indicator

1. Introduction

The purpose of this 510(k) Premarket notification is to obtain premarket clearance for the Verify[®] SYSTEM 1E Chemical Indicator for use in the SYSTEM 1E Liquid Chemical Sterilant Processing System (K090036).

2. Verify[®] SYSTEM 1E Chemical Indicator Configuration

The proposed Verify[®] SYSTEM 1E Chemical Indicator is manufactured by application of the indicator ink by screen printing to a substrate with the indicator ink printed thereon.

3. Principles of Operation

The indicator spot on the proposed Verify[®] SYSTEM 1E Chemical Indicator undergoes a color change from blue to pink when exposed to a SYSTEM 1E Liquid Chemical Sterilization Cycle using S40 Sterilant Concentrate at an in-use peracetic acid concentration of >1820 ppm (mg/L).

As described in the draft Instructions for Use in **Section 13**, a Verify[®] SYSTEM 1E Chemical Indicator can be used by placement in a clip and attachment of the clip to the dedicated peg in the processor tray.

After the cycle is completed, the user inspects the indicator. The indicator is interpreted as a PASS if the indicator ink spot has changed color from the initial blue to a color as pink as or more pink than that color reference indicated as a PASS on the bottle label. If the indicator ink has not changed color, i.e. is still blue, or has changed color to gray/green/beige, the indicator is interpreted as a FAIL, alerting the user that acceptable conditions were not achieved in the cycle.

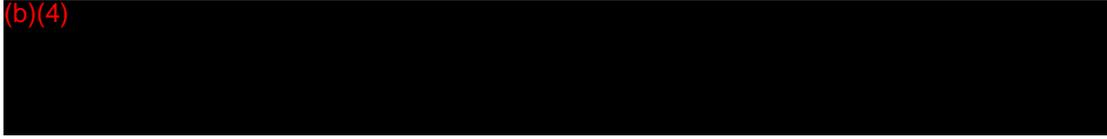
4. Design and Materials

The proposed Verify[®] SYSTEM 1E Chemical Indicator is a chemical indicator strip consisting of indicator ink containing the reactive chemicals printed on one end of a polypropylene strip. A clear, sterilant-permeable polyether block amide laminate is adhesively bonded to the polypropylene strip following printing of the ink, completely covering the ink. The polypropylene strip and laminate are identical to

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

the polypropylene and laminate used for the Verify[®] SPI Chemical Indicator that was cleared for marketing as K052535. The dimensions of the indicator strip are nominally 10 mm x 83 mm.

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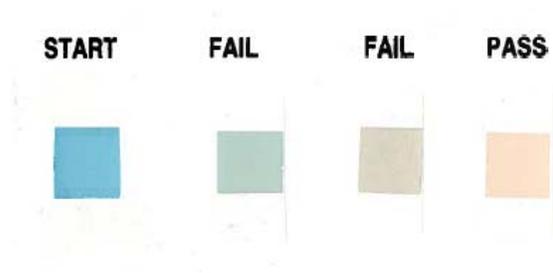
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4.2 Indicator Sample Colors

Below are samples of the indicator colors. Reference blocks used during testing and representative of that which will appear on the device label have been included at the end of this section as a separate page.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**



5. Packaging

The proposed Verify[®] SYSTEM 1E Chemical Indicator is provided non-sterile and will be packaged in an airtight bottle containing a maximum of 60 indicators with an integral desiccant sleeve to absorb moisture. The bottle is a cylindrical snap-top vial made of polypropylene. The proposed Verify[®] SYSTEM 1E Chemical Indicator shall be marketed in a shipper box with two bottles, along with a clip and the Instructions for Use.

Drafts of the bottle label, Instructions for Use and shipper box label are included in **Section 13** of this premarket submission.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**



Verify® Chemical Indicator for SYSTEM 1E™ Processor



8/4/10

STERIS Corporation • 5960 Heisley Road • Mentor, OH 44060-1834 USA • 440-354-2600

Substantial Equivalence Discussion
For
Verify[®] SYSTEM 1E Chemical Indicator

1. Predicate Device

Trade Name:	Verify [®] Chemical Indicator for SYSTEM 1 [®] Sterile Processing System (cleared as Verify [®] SPI Chemical Indicator)
Model Number:	N/A
Common/usual Name:	Chemical Indicator
Classification Name:	Indicator, Chemical Sterilization Process Indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K052535

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
 VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

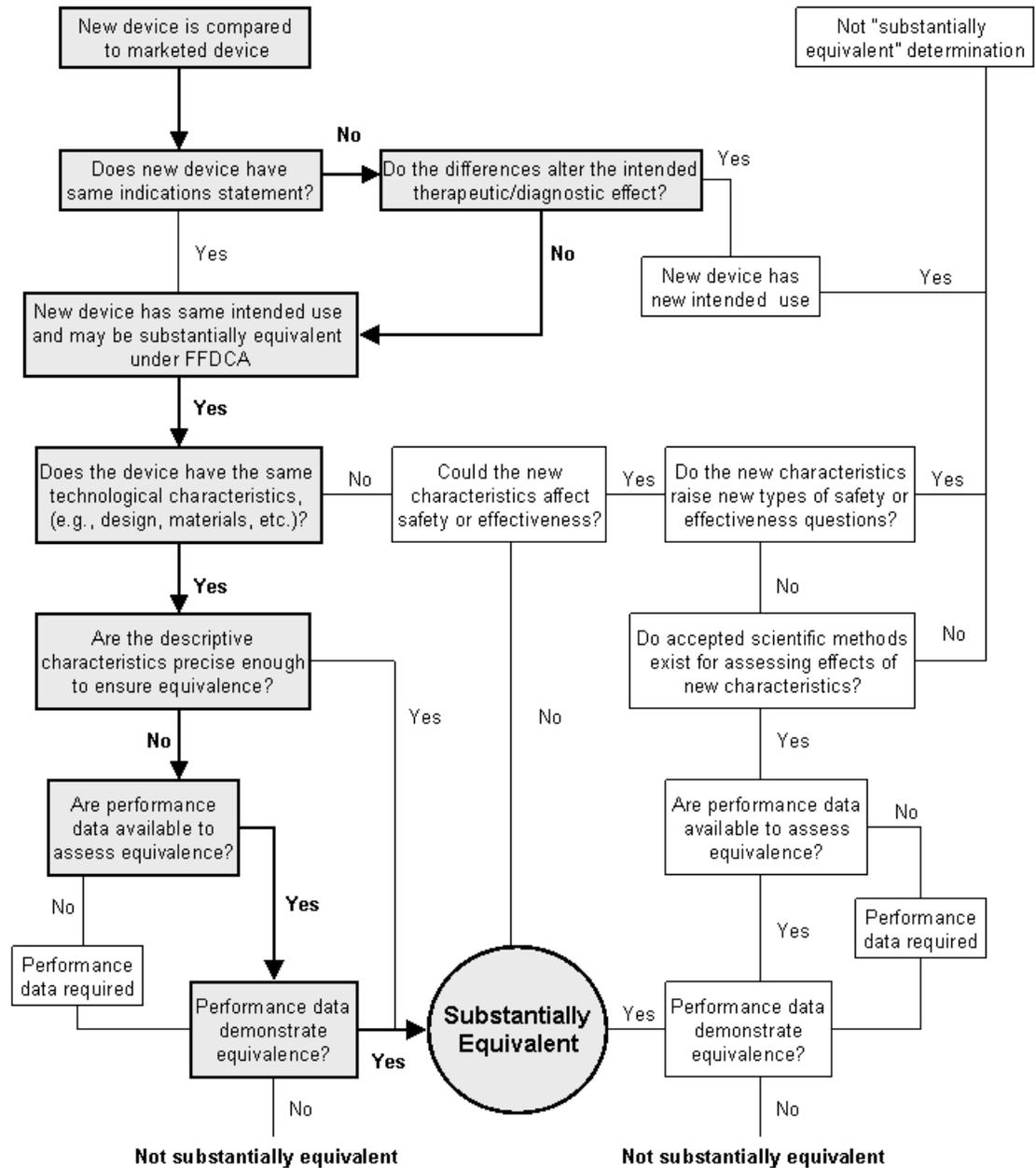
2. Device Comparison Table

Table 12-1. Device Comparison Table

Feature	Proposed Verify® SYSTEM 1E Chemical Indicator	Verify® SPI Chemical Indicator (K052535)
Intended use	Process Indicator for Peracetic Acid	Process Indicator for Peracetic Acid
Device design - components	Printed indicator ink printed on to polypropylene overlaid with a clear, permeable laminate	Printed indicator ink printed on to polypropylene overlaid with a clear, permeable laminate
Indicator agent	(b)(4)	
Sterilization method and cycles	SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate	STERIS SYSTEM 1® Sterile Processing System employing STERIS S20 Sterilant Concentrate
Mechanism of action	(b)(4)	
Peracetic Acid (PAA) Concentration Required for an Endpoint Color Change	> 1820 ppm PAA	> 1800 ppm PAA
Disposable	Yes	Yes
Shelf-life	2 years (proposed)	1 year

3. Substantial Equivalence Decision-Making Process Flowchart

**510(k) "Substantial Equivalence"
 Decision-Making Process**



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

4. Indications for Use Comparison

The Verify[®] SYSTEM 1E Chemical Indicator (SYSTEM 1E Chemical Indicator) is a single use 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 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. Technology

The proposed Verify[®] SYSTEM 1E Chemical Indicator consists of a printed indicator spot on an inert (polypropylene) substrate, where the indicator spot is subsequently encapsulated by lamination with a transparent semi-permeable laminate.

The indicator spot changes color when exposed to a SYSTEM 1E Liquid Chemical Sterilization System cycle. The predicate device, Verify[®] SPI Chemical Indicator, also consists of a printed indicator that changes color when exposed to Liquid Chemical Sterilization.

6. Performance Specifications

The Verify[®] SYSTEM 1E Chemical Indicator and the Verify[®] SPI Chemical Indicator predicate are both process indicators. The proposed and predicate indicators are designed to be mounted to a holder in the SYSTEM 1E Processor and STERIS SYSTEM 1[®] Processor, respectively. The indicators change color during a processing cycle if the peracetic acid concentration in the S40 Sterilant Concentrate and STERIS 20[™] Sterilant Concentrate solutions, respectively, exceed an established value. The peracetic acid concentrations required to produce a color change are similar, being 1820 ppm for the proposed Verify[®] SYSTEM 1E Chemical Indicator and 1800 ppm for the Verify[®] SPI Chemical Indicator.

The mechanism of action for inducing a color change is identical for the proposed Verify[®] SYSTEM 1E Chemical Indicator and the predicate Verify[®] SPI Chemical Indicator. The active ingredients of the ink used for the proposed Verify[®] SYSTEM 1E Chemical Indicator (b)(4) the predicate Verify[®] SPI Chemical Indicator (b)(4) are (b)(4)

(b)(4)
(b)(4) Verify SYSTEM 1E Chemical Indicator, changing the

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



The performance testing supplied in this submission demonstrates that the proposed Verify[®] SYSTEM 1E Chemical Indicator has sufficient specificity and sensitivity to serve as a monitor of the peracetic acid concentration in the S40 Sterilant Concentrate solution when used in the SYSTEM 1E Processor. Differences between the proposed and predicate peracetic acid concentration monitors are limited to minor differences in the indicator ink composition. These differences in technological characteristics do not raise any new issues of safety and effectiveness.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

**Proposed Labeling
For
Verify[®] SYSTEM 1E Chemical Indicator**

Verify[®] Chemical Indicator for SYSTEM 1E[™] Processor

For routine monitoring of SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate

Intended Use

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.

Performance Characteristics

The Chemical Indicator strips for the SYSTEM 1E Processor are used during each processing cycle to detect the presence of the active ingredient, peracetic acid, in the use dilution of S40 Sterilant Concentrate. The unprocessed chemical indicator is blue. When exposed to an effective concentration of peracetic acid found in the sterilant use dilution, the indicator changes color from blue through grey/beige to pink (see the reference colors on the bottle). The indicator's PASS color may become more pink when exposed to higher peracetic acid concentrations in the use dilution of S40 Sterilant Concentrate.

Test data demonstrates that the Verify Chemical Indicator for SYSTEM 1E Processor strips achieve a PASS result when exposed to peracetic acid concentrations greater than the MRC, 1820 mg/L, in use dilution of S40 Sterilant Concentrate within the SYSTEM 1E Processor.

Instructions for Use

1. Check the expiration date on the bottle. Do not use an indicator beyond the expiration date. If a new bottle is being opened, record the date it was first opened and the new 6 month expiration date on the bottle (see Expiration Date).
2. Remove an indicator strip from the bottle and re-close the bottle tightly. Compare the unexposed indicator with the START reference color block on the container. Do not

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

use an indicator if the color of the indicator does not match the START reference color.

3. Using the clip provided, place one strip in a SYSTEM 1E Processor.
4. Start the processing cycle according to the operator manual for the SYSTEM 1E Liquid Chemical Sterilant Processing System.
5. Within 30 minutes of cycle completion, carefully retrieve the indicator strip and compare the indicator color with the reference color blocks on the container.
 - a. If the indicator color is the same as, or more pink than the PASS reference on the container, the processed items may be used.
 - b. If the indicator does NOT meet the criteria defined above (5a), the items must not be used. Follow departmental procedures for reporting failures.

Storage Conditions

Store all unused indicator strips at 43-86°F (6-30°C) and 30-60% relative humidity (RH) in their original, tightly sealed bottles, away from direct light.

Do not store near heat, moisture, strong acids/alkalis, detergents or oxidizing agents.

Exposed indicators can not be maintained as a permanent record.

Expiration Date

The expiration date is stated on the bottle. After first opening the bottle, the shelf life is 6 months from the date opened, or the printed expiration, whichever is shortest. Do not use after the expiration date.

Indicators expire on the last day of the month printed on the label or 6 months after opening, whichever is first.

Performance Limitations

- This product is for single use only. Do not reuse partially processed indicators.
- Verify Chemical Indicators for SYSTEM 1E Processor strips are part of a quality control system for sterility assurance. They cannot be used as a sole means for validating the liquid chemical sterilization process.
- Verify Chemical Indicators for SYSTEM 1E Processor strips should not be used by anyone with color blindness specific to the colors in the indicators. Ensure that all users are able to distinguish processed and unprocessed indicator colors.
- All personnel involved must be trained in the proper use of the indicators and a system for reporting failures must be established.
- If there are any problems interpreting the results from the product, contact STERIS.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Safety Precautions

- This device contains encapsulated dyes, and is safe under normal conditions of use.
- This device is not intended for human consumption.

Disposal Instructions

This product is free from lead and other heavy metals and may be disposed of as regular waste.

Manufactured in the UK
STERIS Corporation
5960 Heisley Road ■ Mentor, OH 44060 USA
440-354-2600 ■ 800- 548-4873

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION VERIFY® SYSTEM 1E CHEMICAL INDICATOR

Bottle Labeling



Date Opened _____ New Expire 6 months, not greater than expiration date.

See the instructions for use **2** Single use only

STERIS Manufactured in the UK
STERIS Corporation
5900 Hershey Road • Mentor, OH 44060 USA
440-354-2500 • 800-540-4873

DIRECTIONS FOR USE

- Place indicator in processor.
- Perform liquid chemical sterilization cycle.
- Within 0 to 30 minutes of cycle completion, compare the indicator color to the reference color blocks on container.

INTERPRETATION

PASS - the indicator is the same as or more pink than the PASS reference.

FAIL - the indicator is not the same as the PASS description above.

See color references below.

VERIFY®
Chemical Indicator for SYSTEM 1E™ Processor
60

For routine monitoring of the SYSTEM 1E Liquid Chemical Sterilant Processing system employing S40 Sterilant Concentrate.

Storage conditions:

STERIS LOT XXXXXX
Exp 2011-11 000006-11-00

Color Reference Chart:

START	FAIL	FAIL	PASS

Sterilization and Shelf Life

For

Verify[®] SYSTEM 1E Chemical Indicator

1. Sterilization

The proposed Verify[®] SYSTEM 1E Chemical Indicator is provided non-sterile.

2. Shelf Life

2.1 Storage

Unused Verify[®] SYSTEM 1E Chemical Indicators should be stored at 43-86°F/6-30°C and 30-60% relative humidity (RH) away from direct sunlight. Indicators should not be stored near steam sterilizers, oxidizing agents or near strong alkaline or acidic products such as cleaning/disinfecting agents. These storage conditions should be maintained after use e.g. when the indicator is filed, however, the processed strip is not intended to be used as a permanent record. These storage instructions are included in the Instructions for Use.

2.2 Expiration Date

The proposed Verify[®] SYSTEM 1E Chemical Indicator should not be used beyond the expiration date printed on the packaging.

2.3 Shelf Life Testing

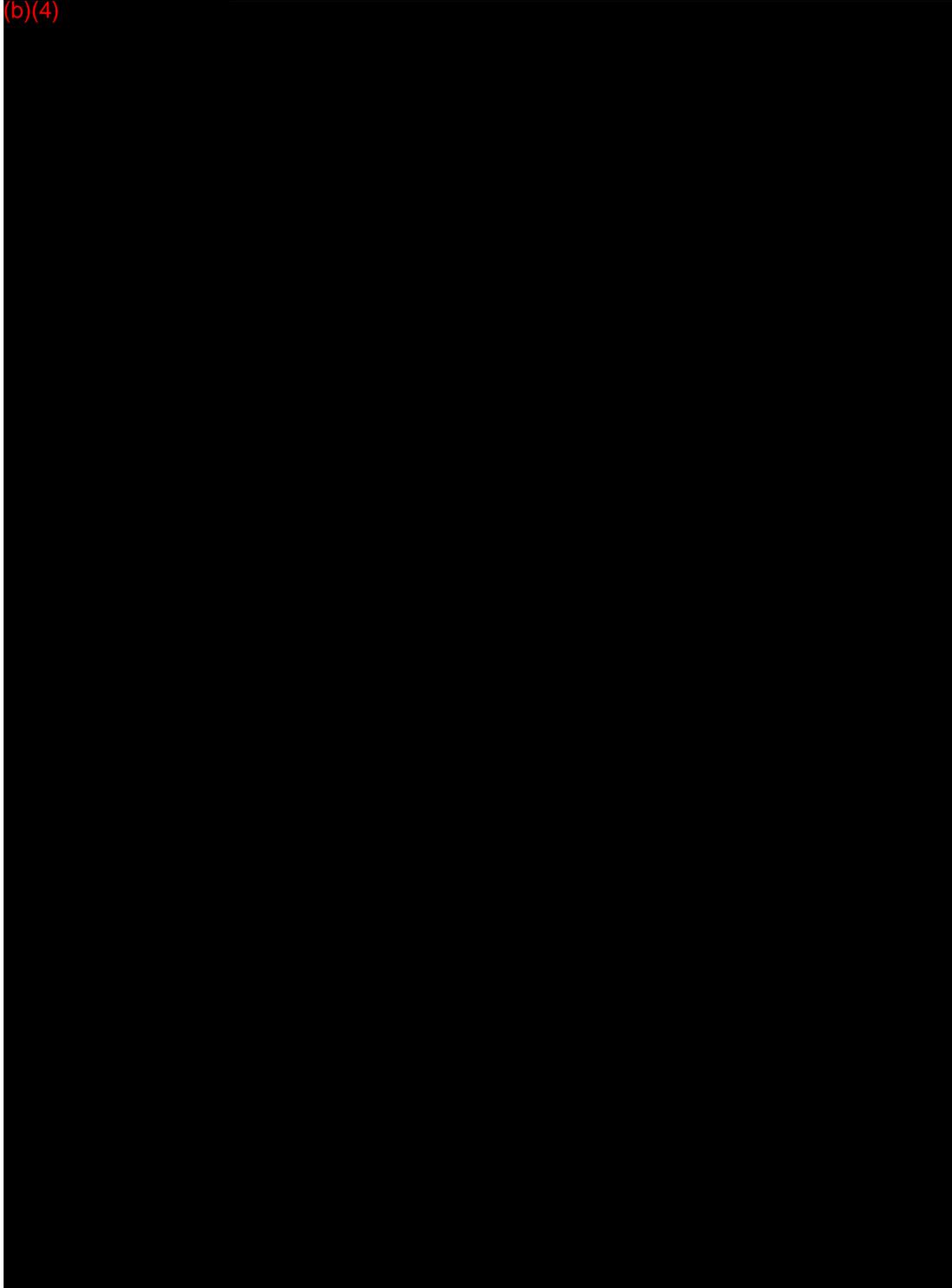
It is the intention of STERIS Corporation to claim a 24 month shelf life for the Verify[®] System 1E Chemical Indicator based on real time stability data. STERIS does not yet have an inventory of the proposed Verify[®] System 1E Chemical Indicator to support the proposed shelf life. Testing for the indicated shelf life time points will be performed in accordance with the procedures outlined in **Appendix A, Section 5.8**. STERIS will perform the shelf life evaluation as described in the protocols to support the proposed 2-year shelf life of the Verify[®] SYSTEM 1E Chemical Indicator. Testing to date, supporting a 15 month shelf life, is described below and also included in **Appendix J**. Until appropriate testing is completed at extended time points, STERIS intends to claim the 15 month shelf life.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

A promissory statement that STERIS will not make shelf-life claims or stability claims without having the supporting testing information is provided as **Appendix O**.

Test Objectives

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



A summary of the 15 month data is presented in Table **14-1**.

The data in **Table 14-1** demonstrates that under a range of storage conditions and for the PAA concentrations to which the strips were exposed, the Verify[®] SYSTEM 1E Chemical Indicators can correctly identify PASS or FAIL conditions for PAA concentrations in the SYSTEM 1E Liquid Chemical Sterilant Processing System.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)

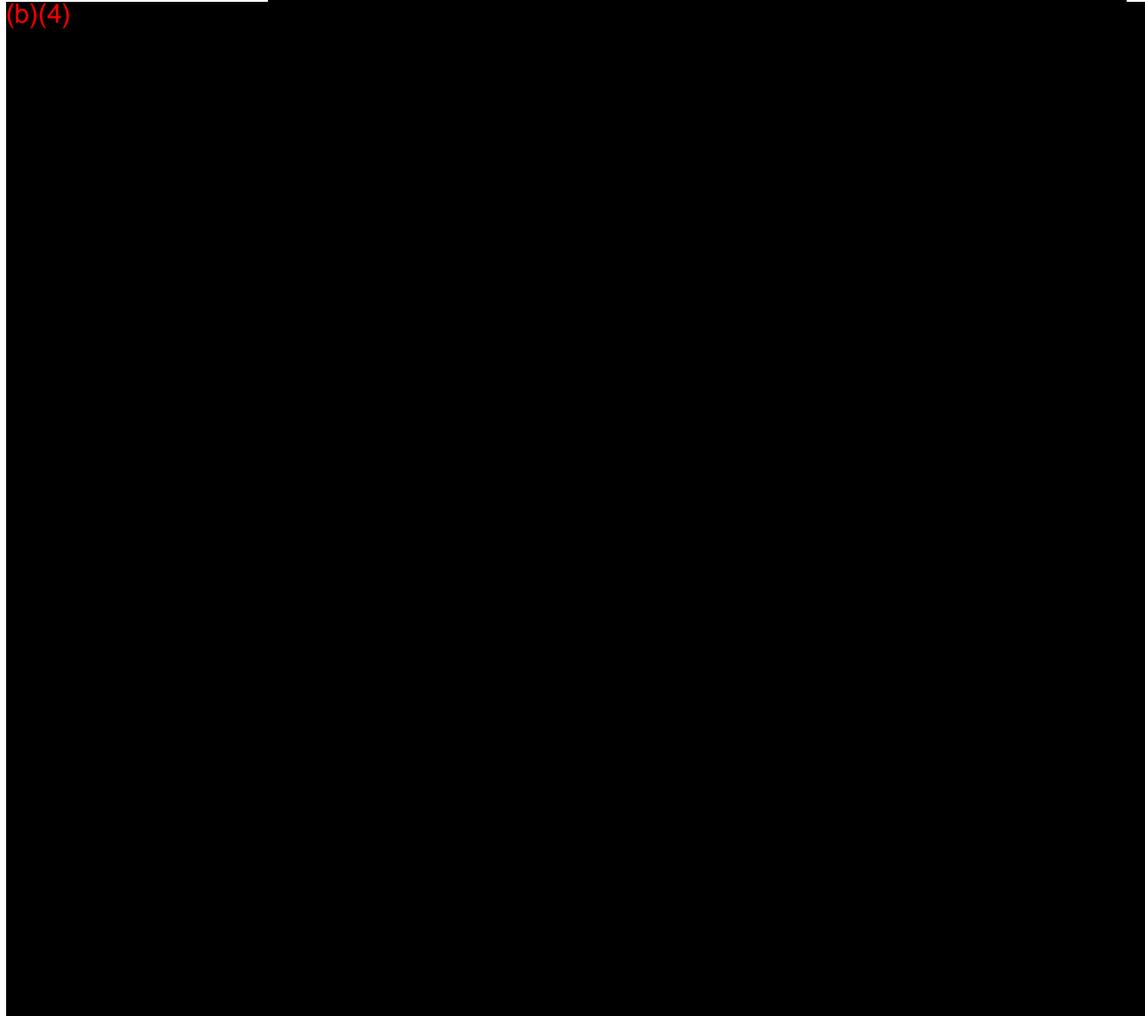
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It is concluded that the Verify[®] SYSTEM 1E Chemical Indicator maintains its characteristics after 15 months of storage. Therefore, STERIS intends to claim this 15 month shelf life at the time of this submission.

2.4 Open Bottle Stability Testing

It is the intention of STERIS Corporation to claim a 6 month shelf life for the Verify[®] System 1E Chemical Indicator following opening of the bottle. This claim shall be based on real time stability data. STERIS does not yet have data based on the current test system to support the proposed open bottle stability claim. However (b)(4)

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

**Biocompatibility
For
Verify® SYSTEM 1E Chemical Indicator**

The Verify® SYSTEM 1E Chemical Indicator does not contain components that come into direct or indirect contact with patients.

The Verify® SYSTEM 1E Chemical Indicator consists of reactive chemicals printed on one end of a polypropylene strip. A clear, sterilant-permeable polyether block amide laminate is adhesively bonded to the polypropylene strip following printing of the ink, completely covering the ink.

A Hazard Analysis for the proposed Verify® SYSTEM 1E Chemical Indicator is included in **Appendix N**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

**Software
For
Verify[®] SYSTEM 1E Chemical Indicator**

This section does not apply

Electromagnetic Compatibility and Electrical Safety
For
Verify[®] SYSTEM 1E Chemical Indicator

This section does not apply

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Performance Testing - Bench For Verify[®] SYSTEM 1E Chemical Indicator

Overview

The proposed Verify[®] System 1E Chemical Indicator was tested to demonstrate compliance with performance requirements for the SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate. **Table 18-1** lists the associated reports for the testing described herein. Each of the referenced documents is provided as the listed Appendix to this submission.

Table 18-1. Proposed Verify[®] System 1E Chemical Indicator Reports and Appendices

Testing	Report Number(s)	Appendix
Comparative Sensitivity and Specificity	10028892	C
Color Read Time if Removal from the Processor is Delayed	10028893	D
Color Read Time Immediately After The Processor Cycle	10028894	E
Analytic Specificity	10028865	F
Blind Reader	10028753	G
Simulated Use Testing	10028897	H
UV Study	11028898	I
Shelf Life	10028999	J
Effects of Aggressive Chemicals	11028900	K
Effects of Contaminants	10028901	L
Open Bottle Stability	RDP.154SSL4, 5 & 6	M
Toxicity Analysis	N/A	N

General Test System

The indicators were evaluated by being processed in a SYSTEM 1E Processor with the S40 Sterilant Concentrate containers, made by (b)(4)

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Table 18-3. Color Read Evaluation for Comparative Sensitivity and Specificity

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(b)(4)

Conclusions

Values of 1.00 for the sensitivity and specificity demonstrate that for the PAA concentrations at which the Verify[®] SYSTEM 1E Chemical Indicator strips were exposed the indicators can correctly identify PASS or FAIL conditions for PAA concentrations in the SYSTEM 1E Liquid Chemical Sterilant Processing System.

Color Read Time Immediately After the Processor Cycle

The final report describing the performance testing for when the color read of the Verify[®] SYSTEM 1E Chemical Indicator is taken immediately after the processor cycle is provided in **Appendix D** of this submission.

Test Objective

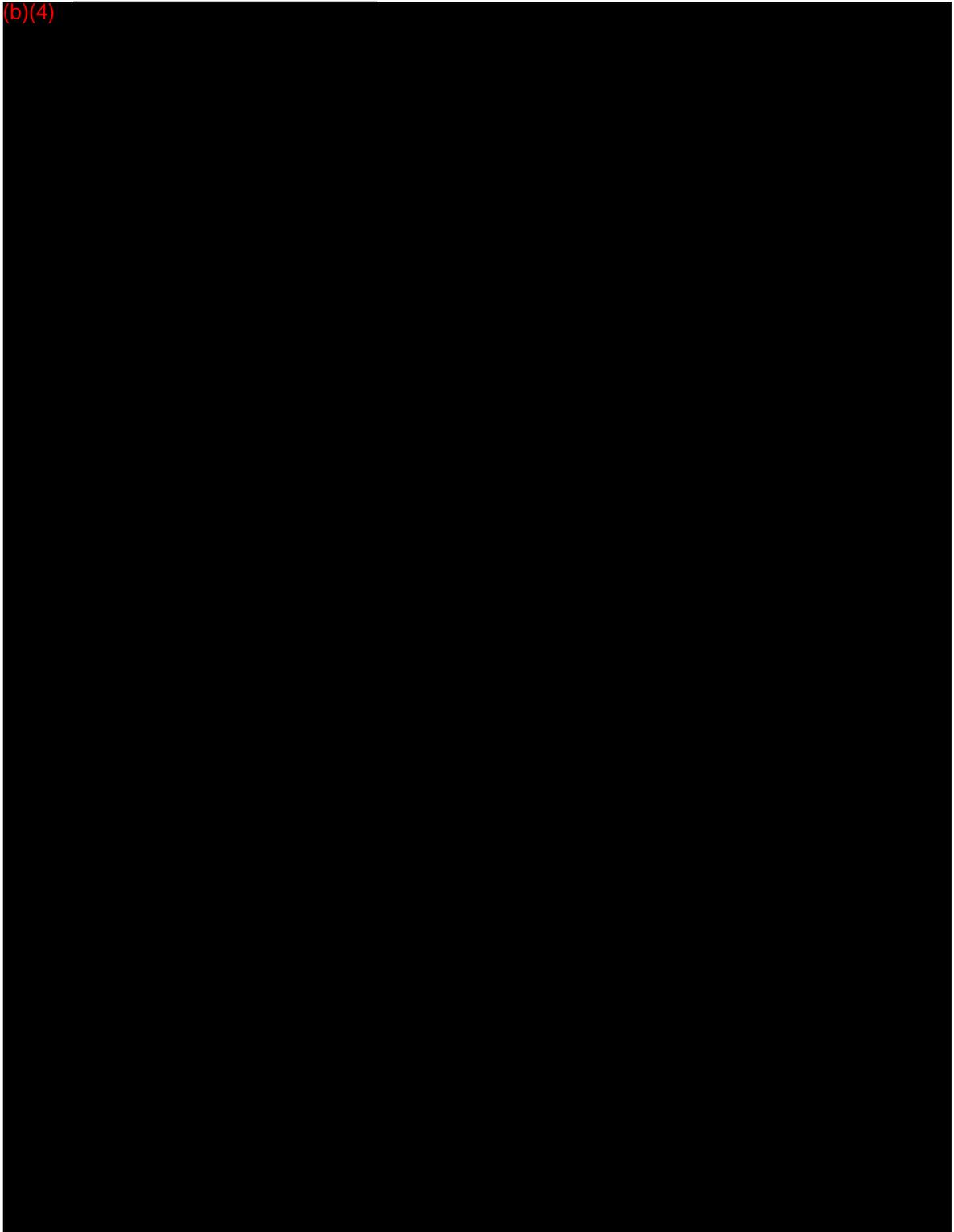
The purpose of this study was to determine the time interval required within which a user must interpret the color change results after removal of Verify[®] SYSTEM 1E Chemical Indicators from the SYSTEM 1E Processor.

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**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Test Methods and Procedures

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A summary of the data is presented in **Table 18-4**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

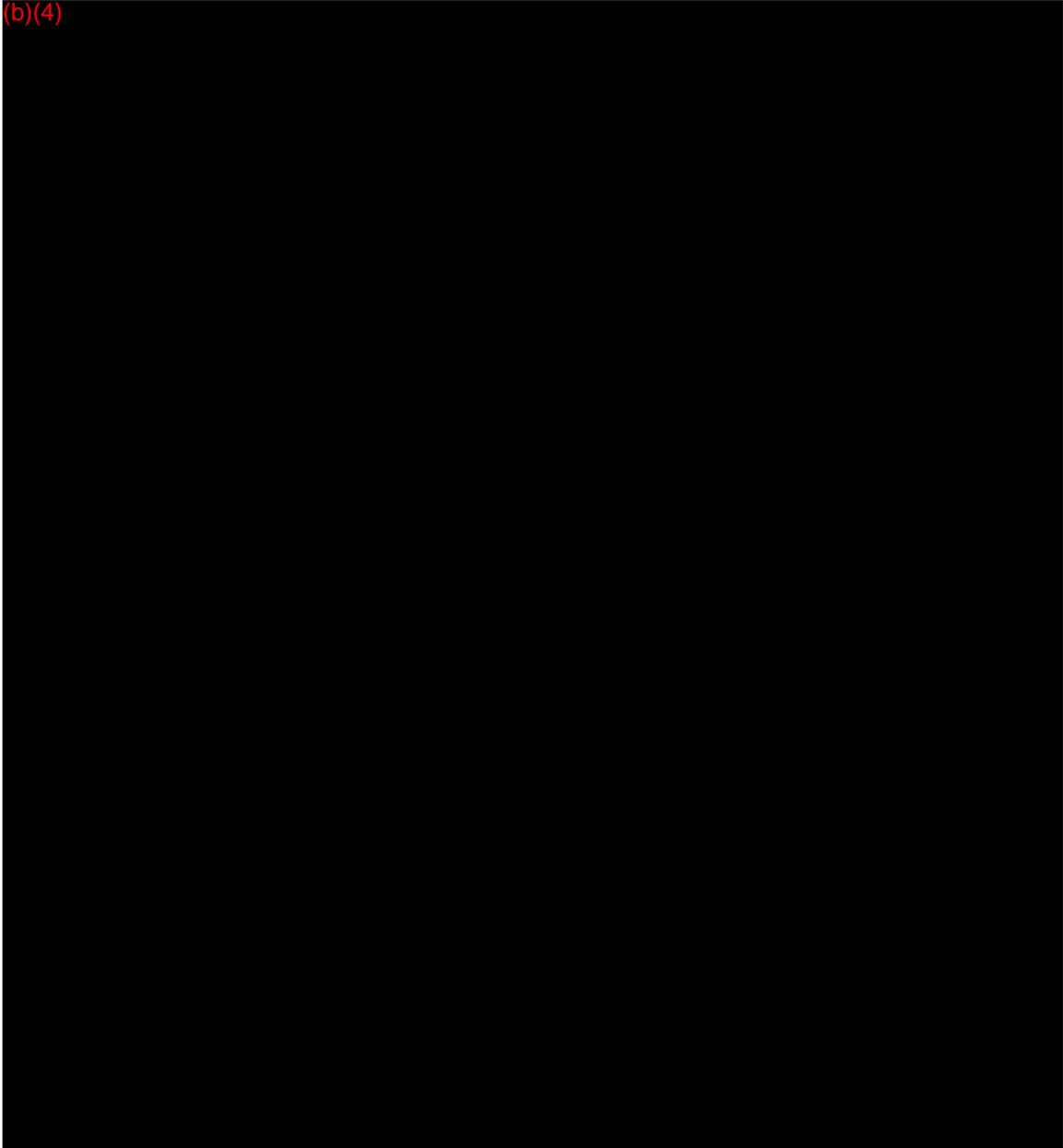
Test Objective

The objective of this study was to determine the time required within which a user must interpret the color change results of the Verify[®] SYSTEM 1E Chemical Indicator after a delay in opening the SYSTEM 1E Processor container.

Test Articles

Each cycle testes used a minimum of 15 strips from each of the 3 lots (across 2

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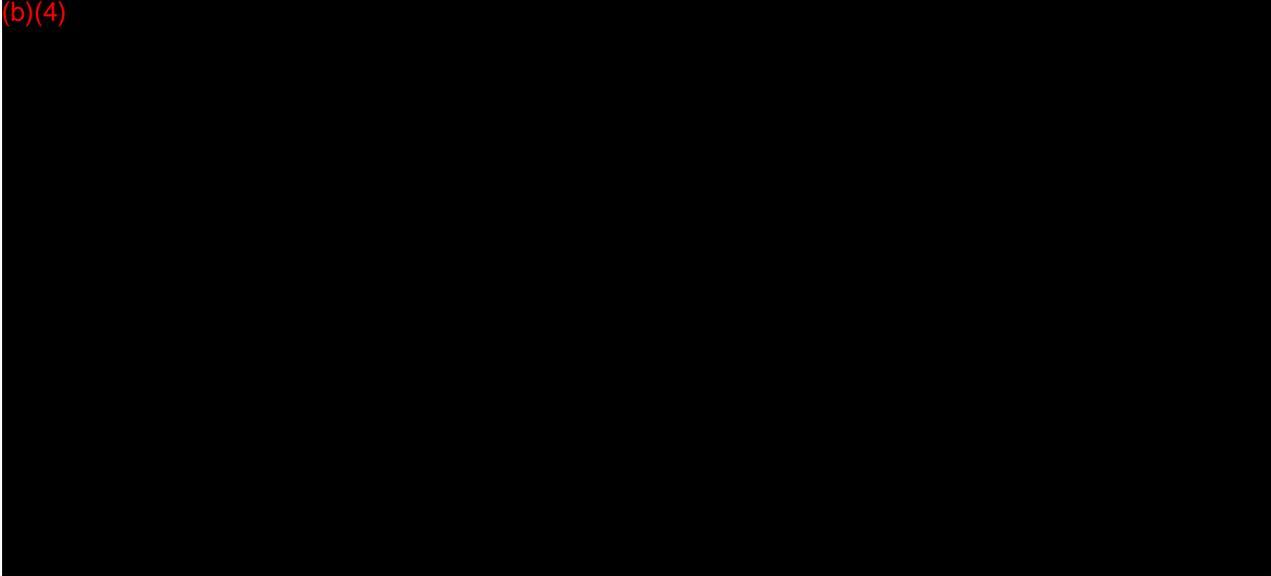


Results

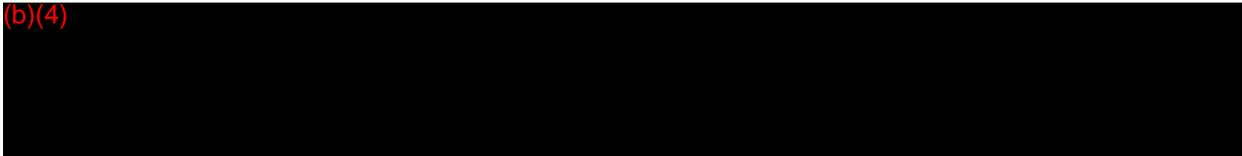
A summary of the data is presented in **Table 18-5**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



(b)(4)



(b)(4)

Therefore, *it is recommended that the PASS/FAIL evaluation be immediately after the CI strip is removed from the processor at the completion of the cycle*, but a delayed evaluation time of 30 minutes is acceptable if the processor remains unopened after completion of the cycle.

Analytic Specificity

The report detailing the analytic specificity of the Verify® System 1E Chemical Indicator is provided in **Appendix F** of this submission.

Test Objective

Verify that the color change in the indicator is specific to PAA when used in the SYSTEM 1E Processor.

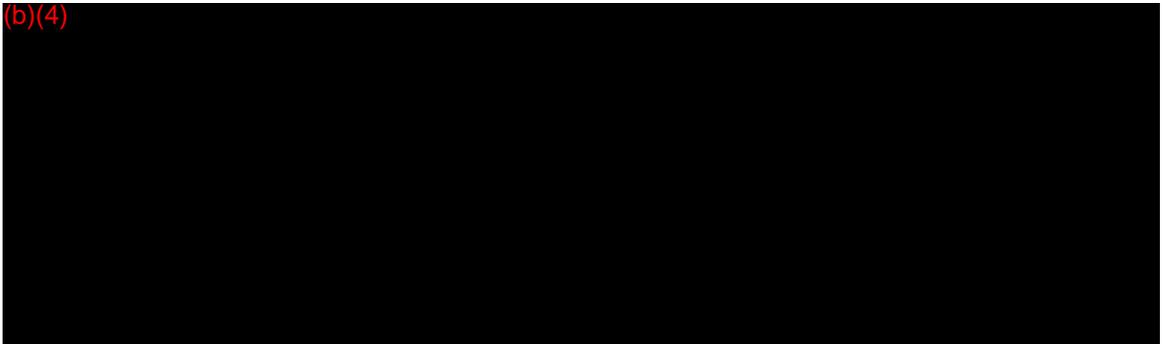
Test Articles

A minimum of 30 Verify® SYSTEM 1E Chemical Indicator strips from each of

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(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

in the same manner as above. The color evaluation of the processed strips was

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(b)(4)



Conclusions

Under conditions of normal storage and use, as indicated in the labeling, any color change observed in a processed CI strip will be the result of the presence of PAA in the processor use dilution.

Blind Reader Testing

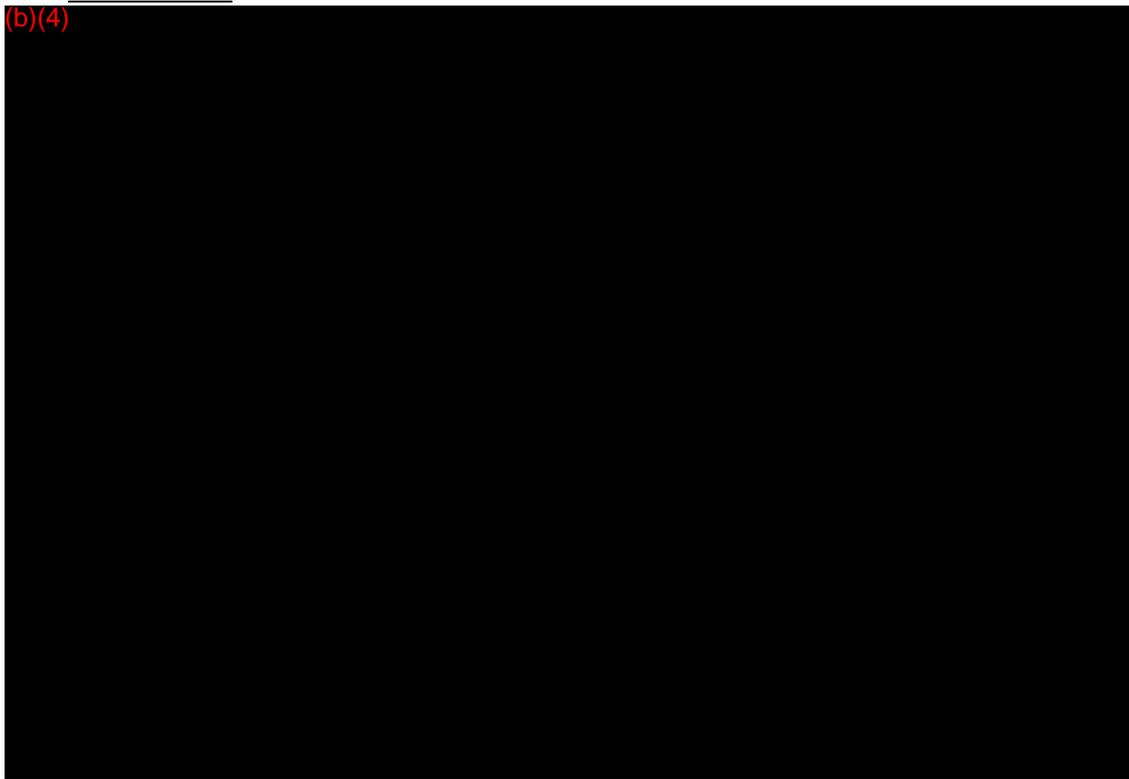
The final report describing the blind study testing for the Verify® System 1E Chemical Indicator is provided in **Appendix G** of this submission.

Test Objective

To verify that the processed indicator color is interpreted correctly by readers who do not know what PAA concentration the strips were exposed to during a SYSTEM 1E Processor cycle.

Test Articles

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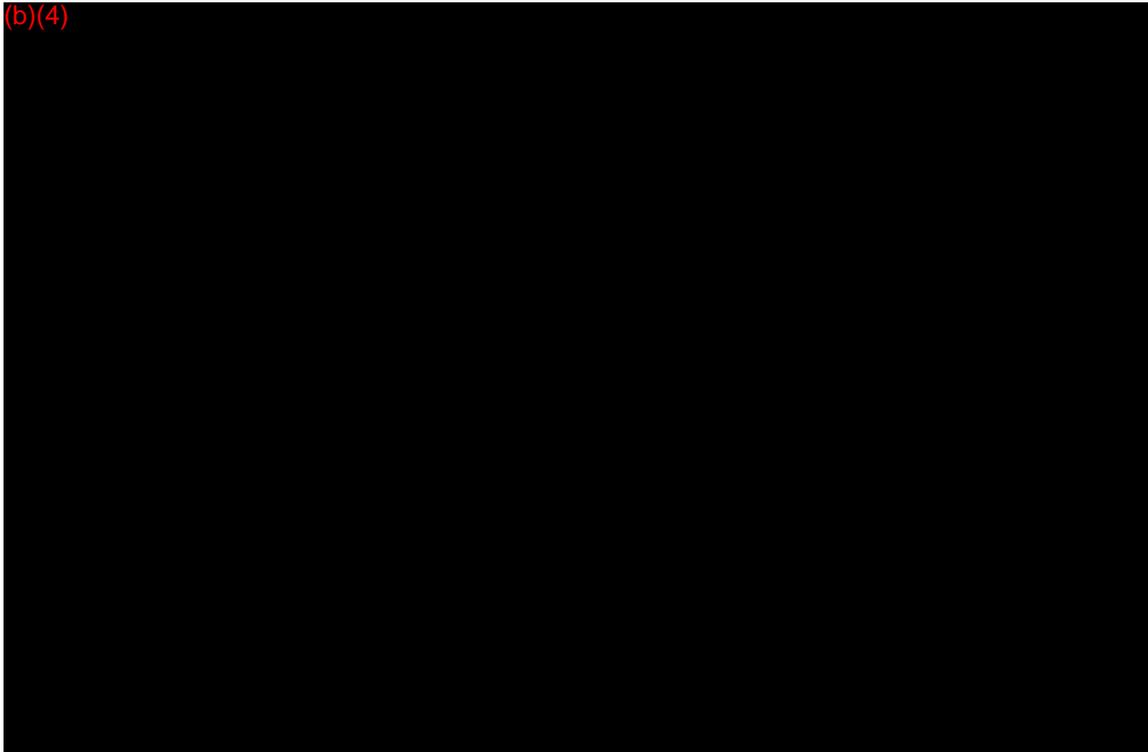
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

holding 117.7 ± 2.4 g of ABC Builders. This container was added to the

(b)(4)



(b)(4)



Results

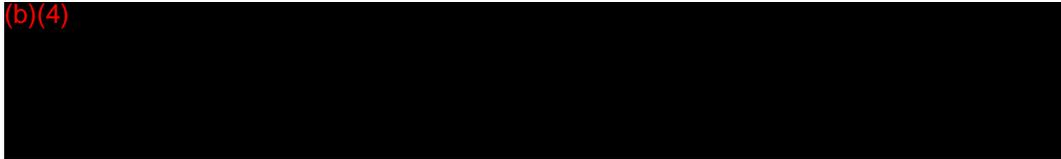
All 90 of the 90 Verify® SYSTEM 1E Chemical Indicator strips exposed to the manufacturing target fill S40 Sterilant Concentrate resulted in a color change that was evaluated by the three readers as a PASS, when compared to the Reference color squares.

All 90 of the 90 strips exposed to the MRC concentration of S40 Sterilant Concentrate resulted in a color change that was evaluated by the three readers as a FAIL, when using the Reference color squares.

A summary of the data is presented in **Table 18-6**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



From this study, it is concluded that the CI strips can effectively demonstrate 100% FAIL at or just below MRC and 100% PASS at a concentration above MRC.

Simulated Use Testing

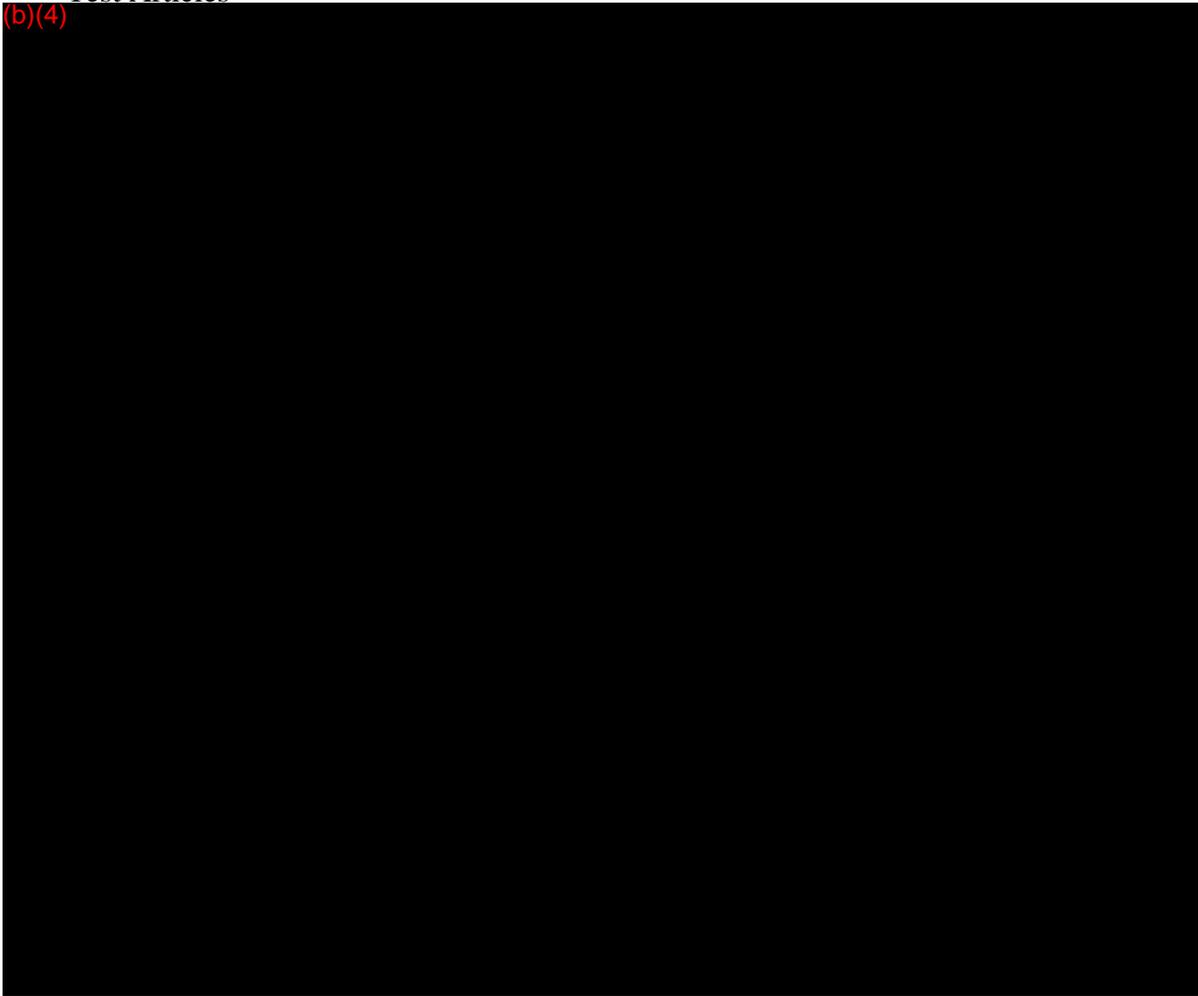
The final report describing the completed simulated use testing for the Verify[®] SYSTEM 1E Chemical Indicator is provided in **Appendix H** of this submission.

Test Objective

The objective of this study was to determine the performance of the Verify[®] SYSTEM 1E Chemical Indicator under simulated use conditions by evaluating the effects that placing an endoscope in the SYSTEM 1E processor device container might have on the indicator strip performance.

Test Articles

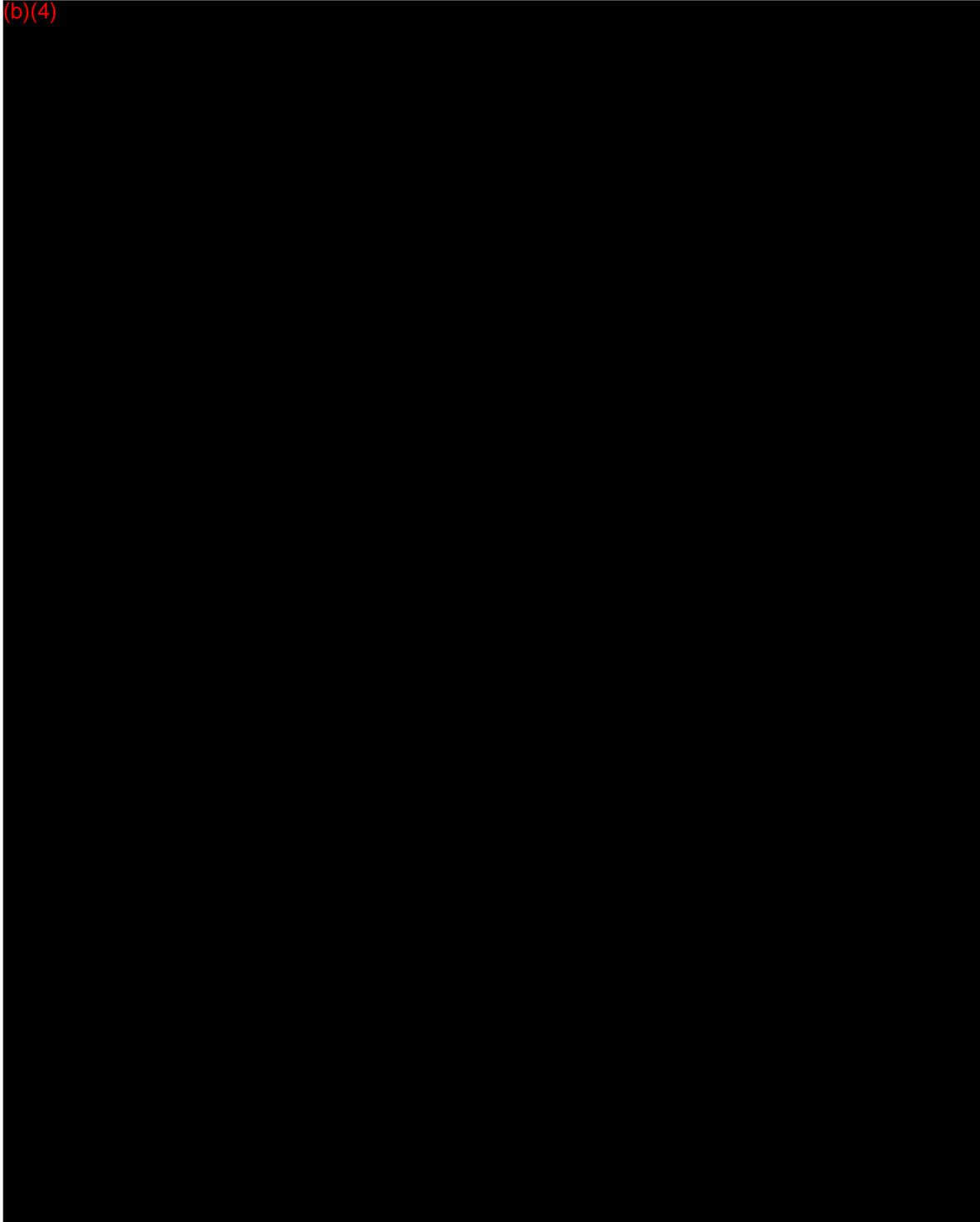
(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

MRC was reduced.] The container was then inserted into the container
(b)(4)

(b)(4)



Conclusions

The addition of a medical device to the processing chamber does not affect the performance of the CI strips.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

UV Light Exposure Testing¹

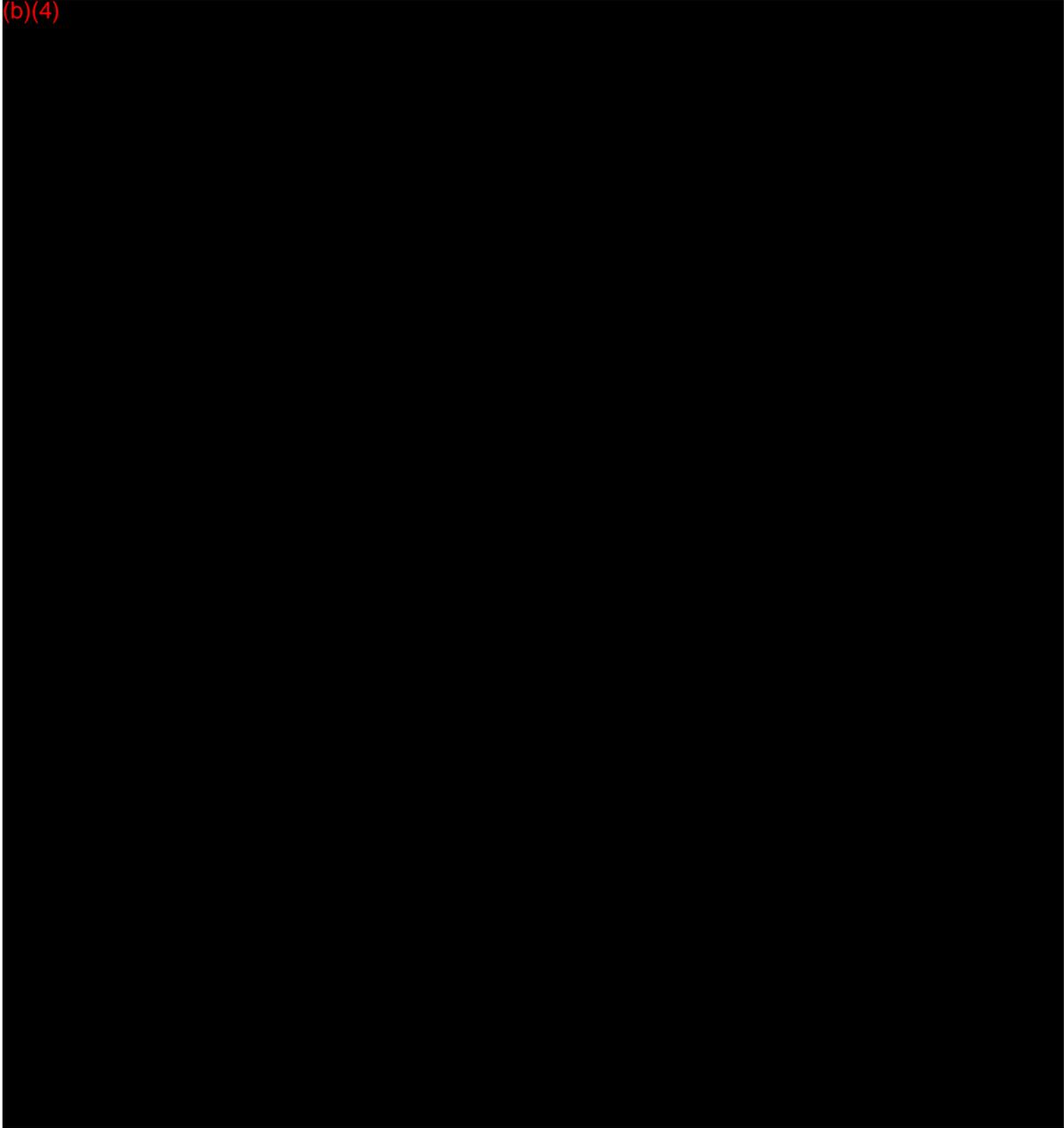
The final report describing the completed UV radiation testing for the Verify[®] SYSTEM 1E Chemical Indicator is provided in **Appendix I** of this submission.

Test Objectives

The purpose of this study was to evaluate the effects that direct UV radiation has on the Verify[®] SYSTEM 1E Chemical Indicator strip prior to use in the SYSTEM 1E Processor.

Test Articles

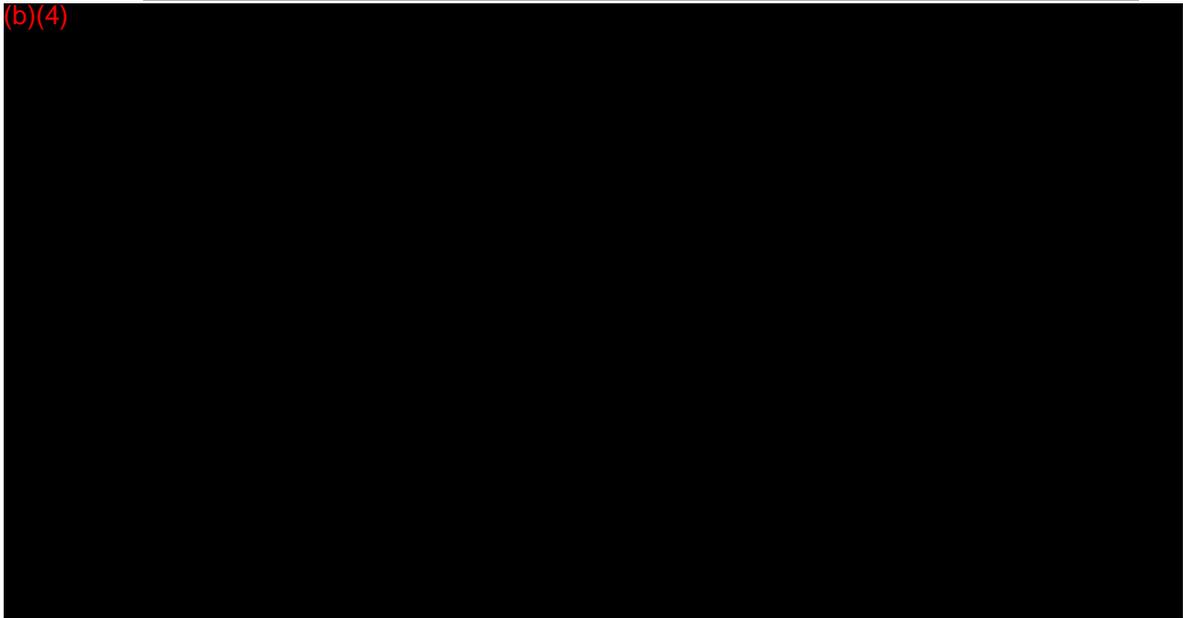
(b)(4)



¹ The SYSTEM 1E Liquid Chemical Sterilant Processing System includes a water treatment system that utilizes an ultraviolet light source.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

bench top for comparison to the START color reference. The color



Conclusions

This study demonstrated that the bottle used to ship and store the chemical indicator strips designed for use in the SYSTEM 1E Processor protects the unprocessed strips from the effects of UV light.

A change in the START color was observed in unprocessed strips when exposed to UV light. No color change was observed if the strips were stored in closed bottles. *Unprocessed strips should be kept in the shipping and storage bottle until ready for use in the SYSTEM 1E Processor* so the unprocessed strips will be protected from UV light exposure and the observed color change of the processed CI strip will be reliable. *Unprocessed strips should always be compared to the START Reference square prior to use.*

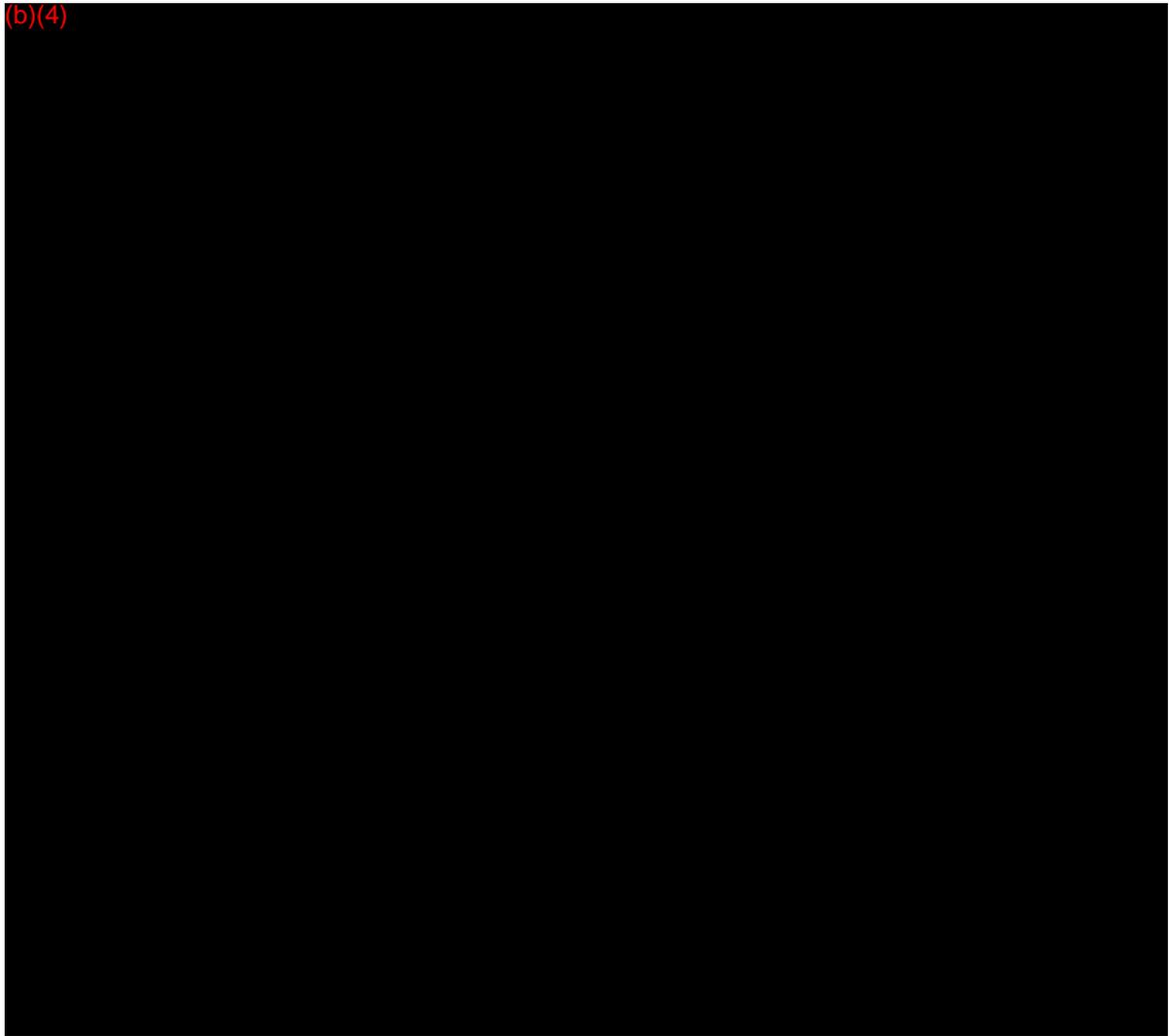
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Shelf Life Testing

It is the intention of STERIS Corporation to claim a 24 month shelf life for the Verify[®] SYSTEM 1E Chemical Indicator based on real time stability data. STERIS does not yet have an inventory of the proposed Verify[®] SYSTEM 1E Chemical Indicator to support the proposed shelf life. Testing for the indicated shelf life time points will be performed in accordance with the procedures outlined in **Appendix A, Section 5.8**. STERIS will perform the shelf life evaluation as described in the protocols to support the proposed 2-year shelf life of the Verify[®] SYSTEM 1E Chemical Indicator. Testing to date, supporting a 15 month shelf life, is described below and also included in **Appendix J**. Until appropriate testing is completed at extended time points, STERIS intends to claim the 15 month shelf life.

A promissory statement that STERIS will not make shelf-life claims or stability claims without having the supporting testing information is provided as **Appendix O**.

(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

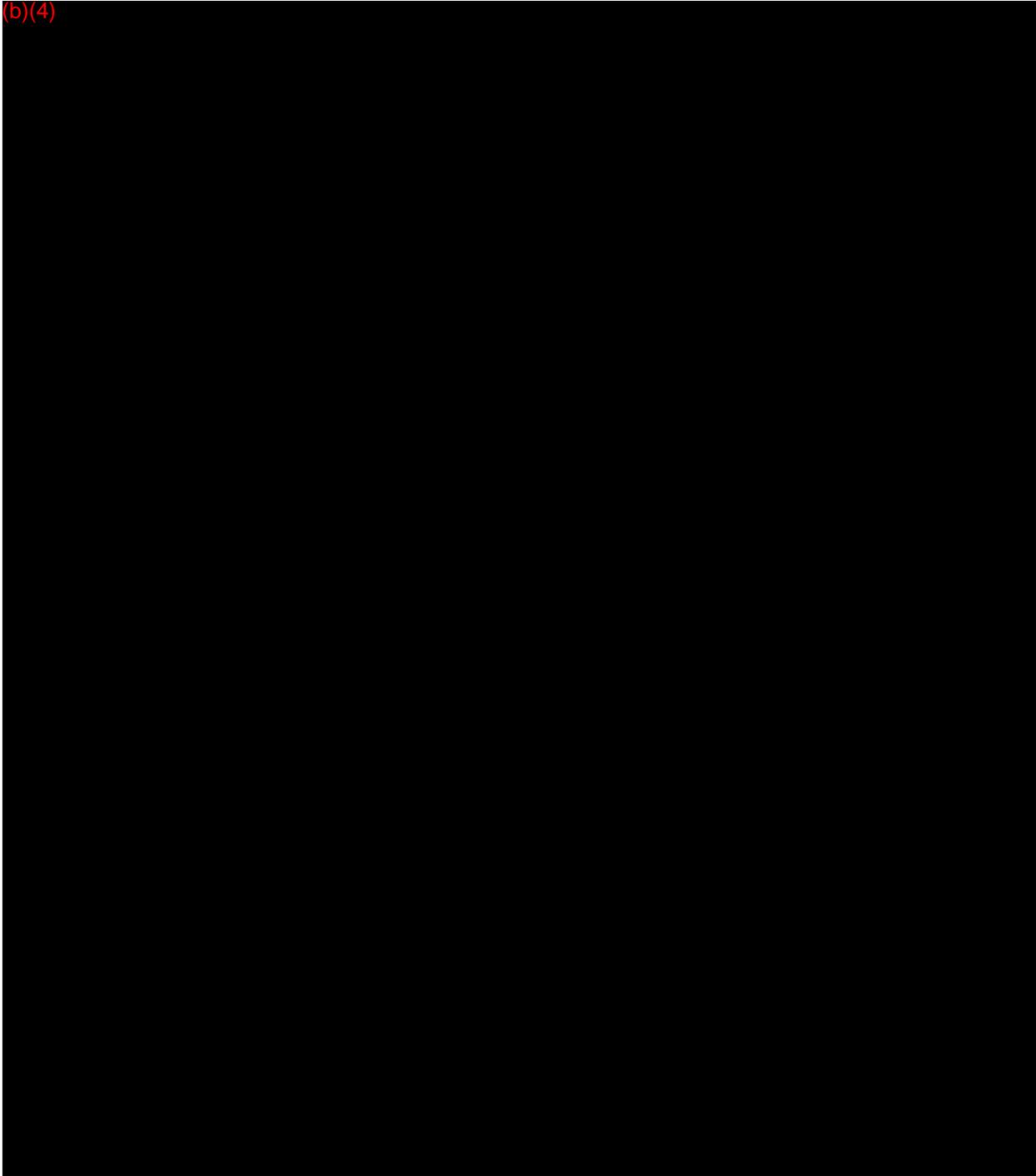
(b)(4)



A summary of the 15 month data is presented in Table **18-8**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)

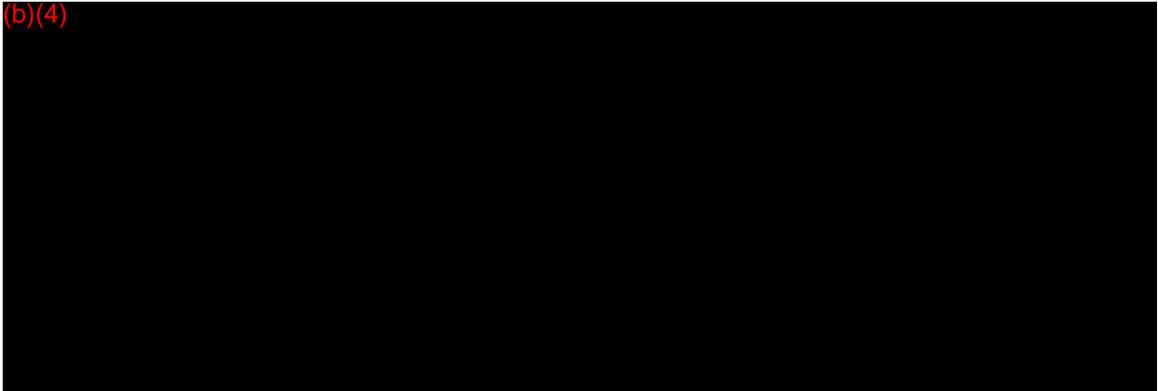


The data in **Table 18-8** demonstrates that under a range of storage conditions and for the PAA concentrations to which the strips were exposed, the Verify[®] SYSTEM 1E Chemical Indicators can correctly identify PASS or FAIL conditions for PAA concentrations in the SYSTEM 1E Liquid Chemical Processing System.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Conclusions

(b)(4)



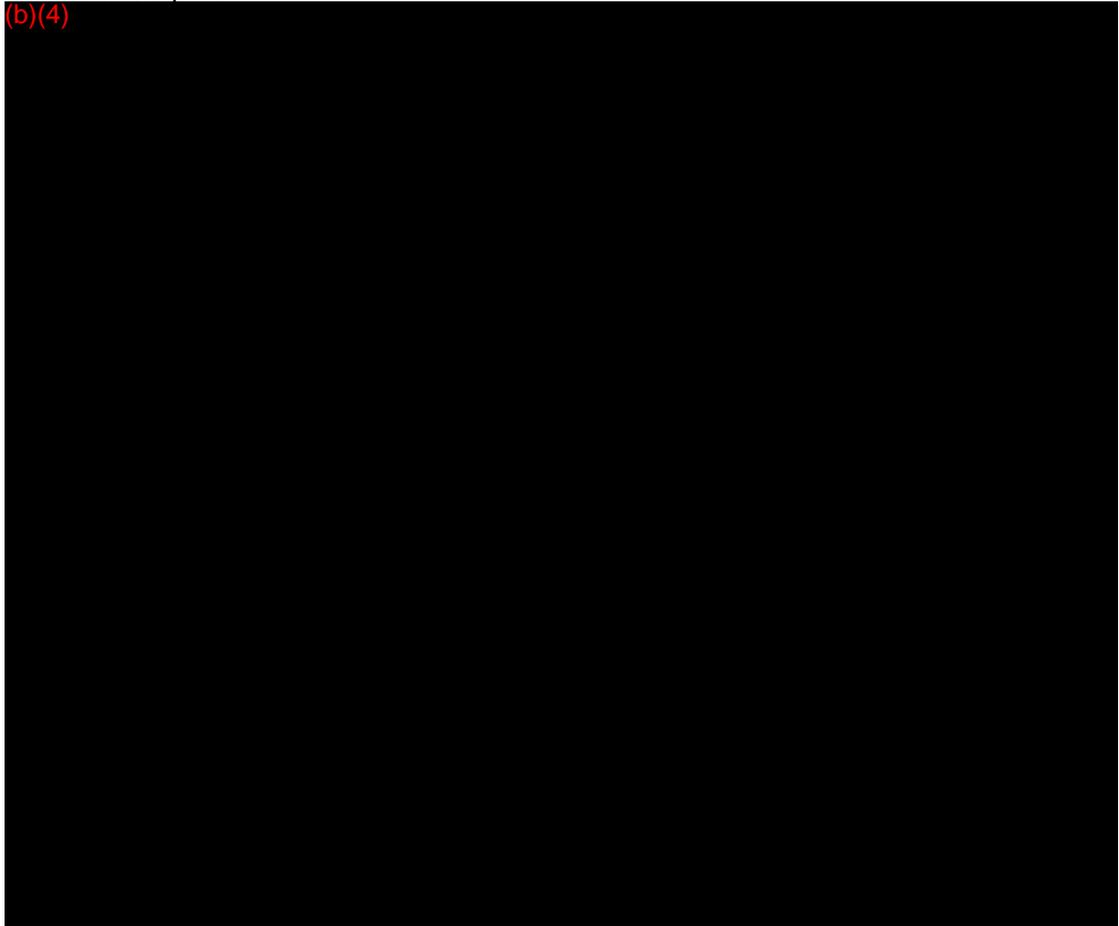
It is concluded that the Verify[®] SYSTEM 1E Chemical Indicator maintains appropriate indicator characteristics after 15 months of storage. Therefore, STERIS intends to claim this 15 month shelf life at the time of this submission.

Aggressive Chemical Stability Testing

The final report describing aggressive chemical stability testing for the Verify[®] SYSTEM 1E Chemical Indicator is provided in **Appendix K** of this submission.

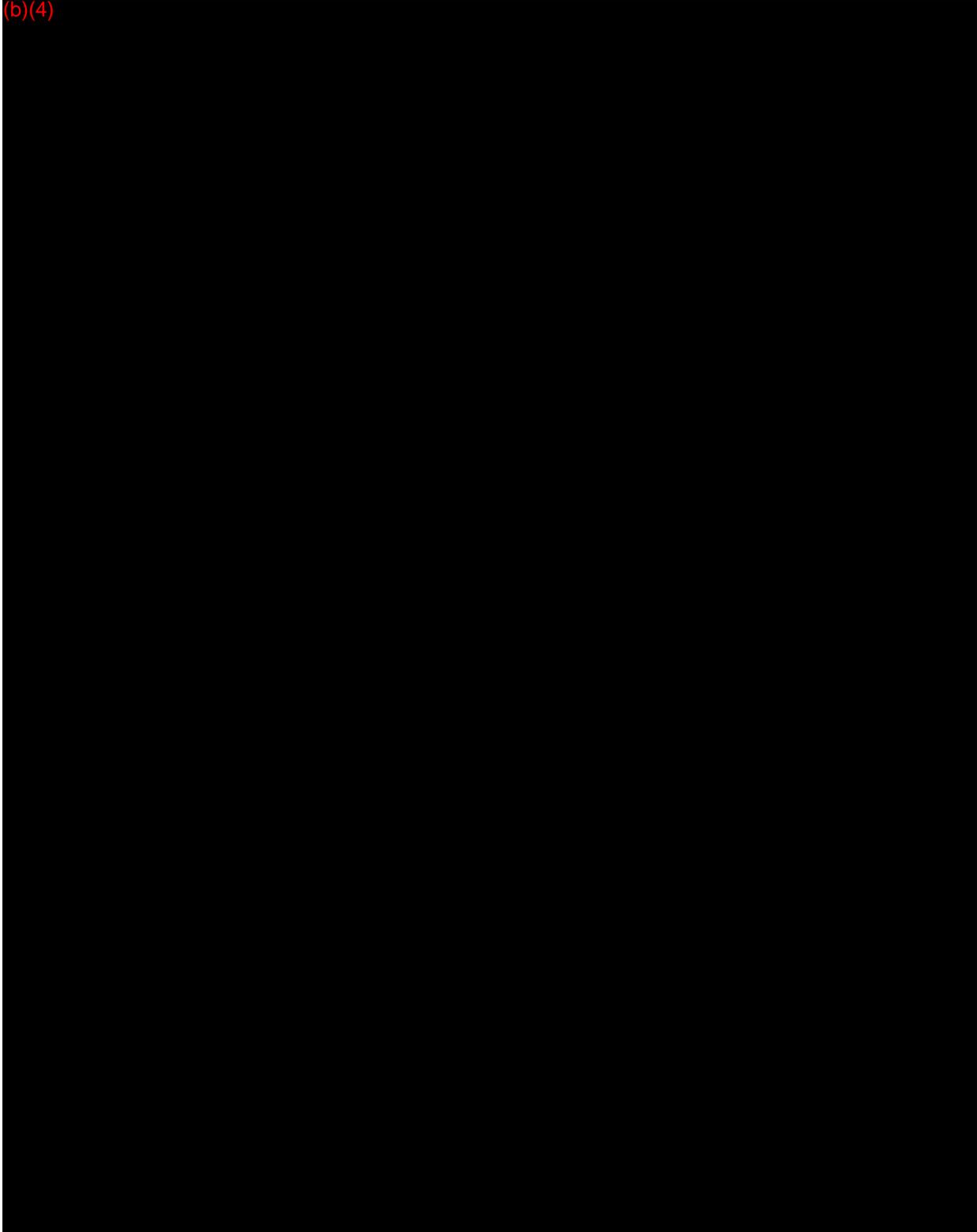
Test Objectives

(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



Conclusions

This study demonstrated that the bottle used to ship and store the Verify[®] System 1E Chemical Indicator strips designed for use in the SYSTEM 1E

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

Processor protects the unprocessed strips from the effects of aggressive chemicals. Therefore, unprocessed strips should be kept in the closed storage bottle provided until use and always be compared to the START Reference square prior to use.

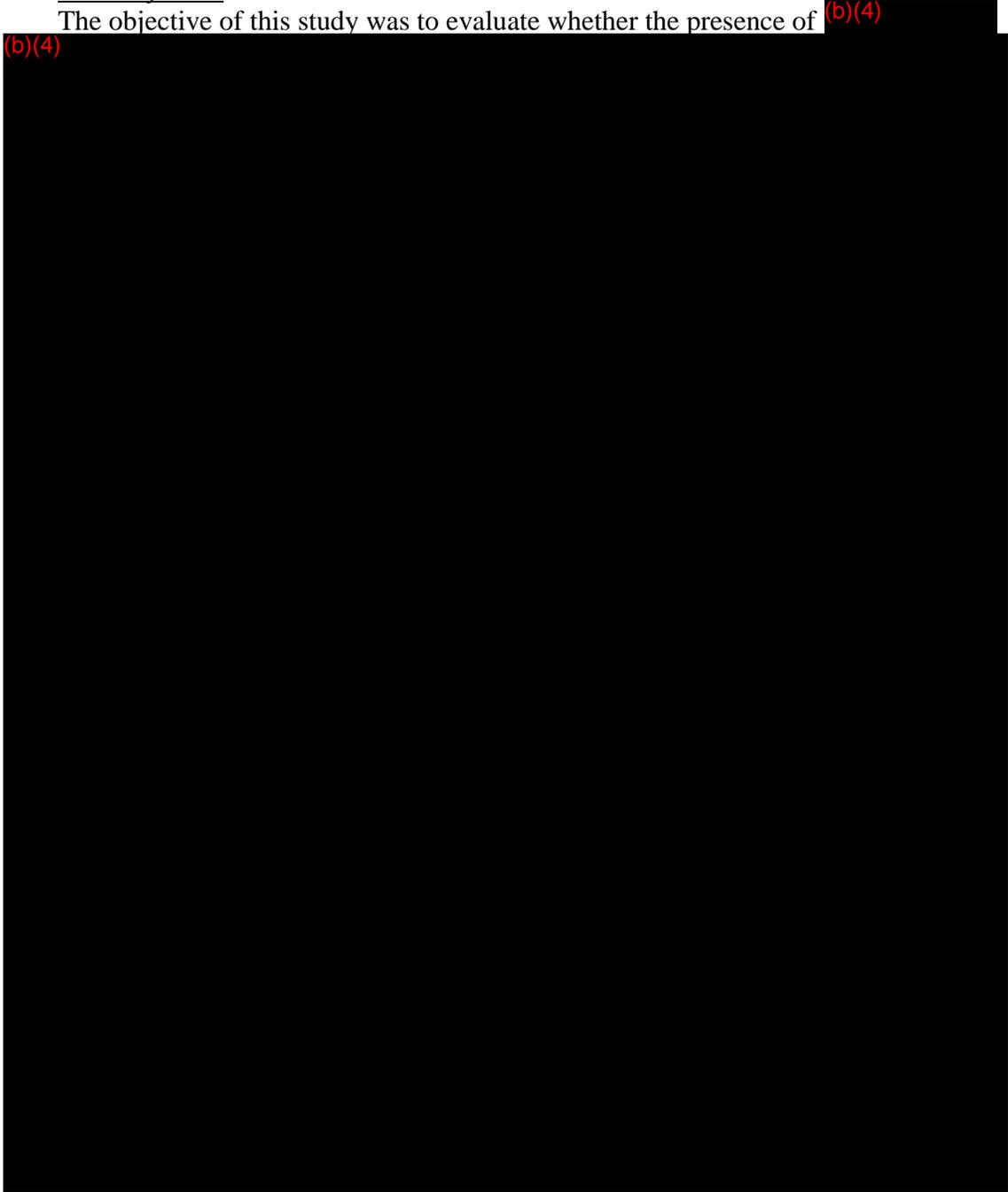
Contaminants Testing

The final report describing the completed contaminants testing for the Verify[®] System 1E Chemical Indicator is provided in **Appendix L** of this submission.

Test Objective

The objective of this study was to evaluate whether the presence of (b)(4)

(b)(4)



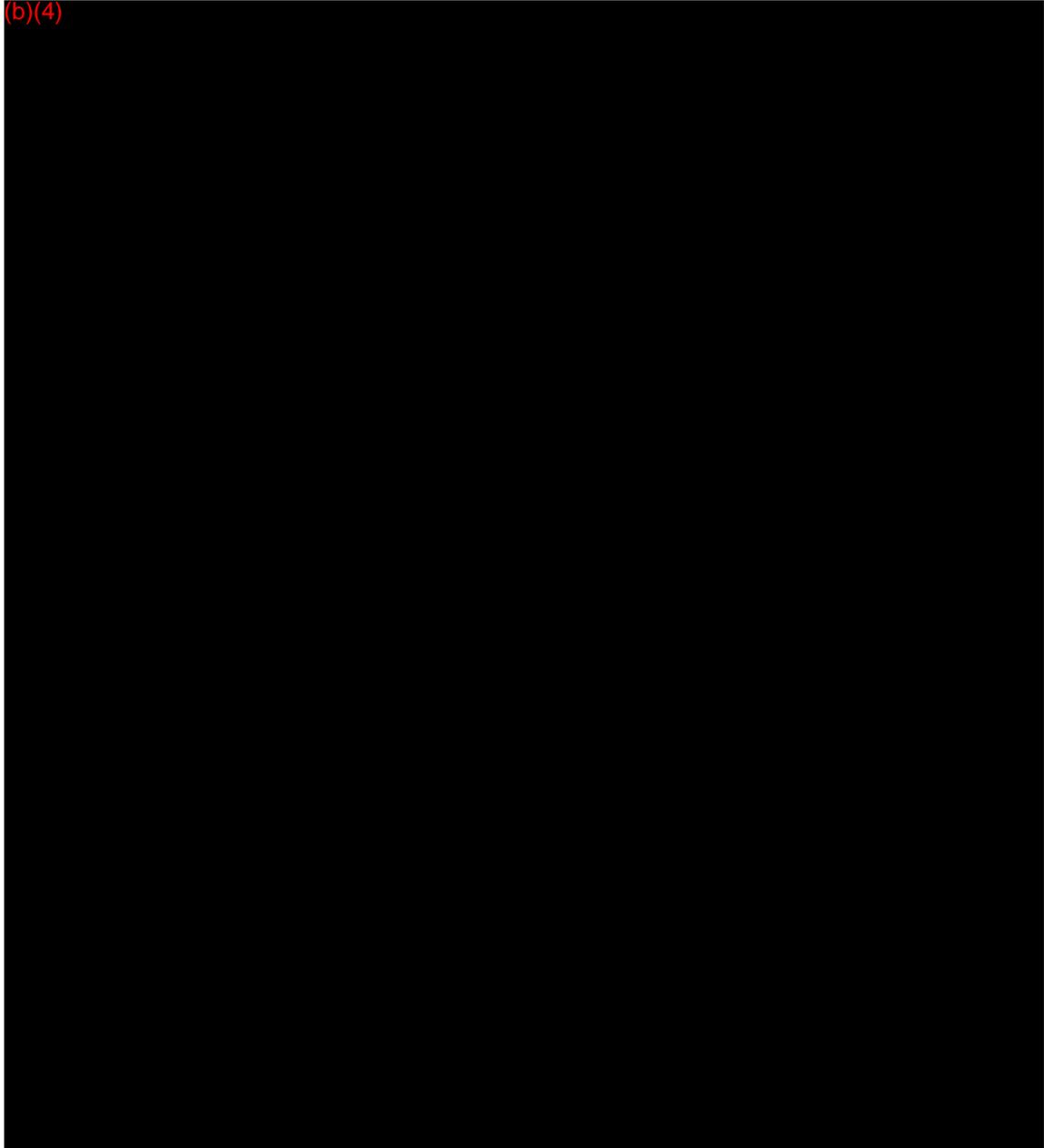
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

C1200E cassette. The cassette lid was closed and placed in the tray installed in

(b)(4)



(b)(4)

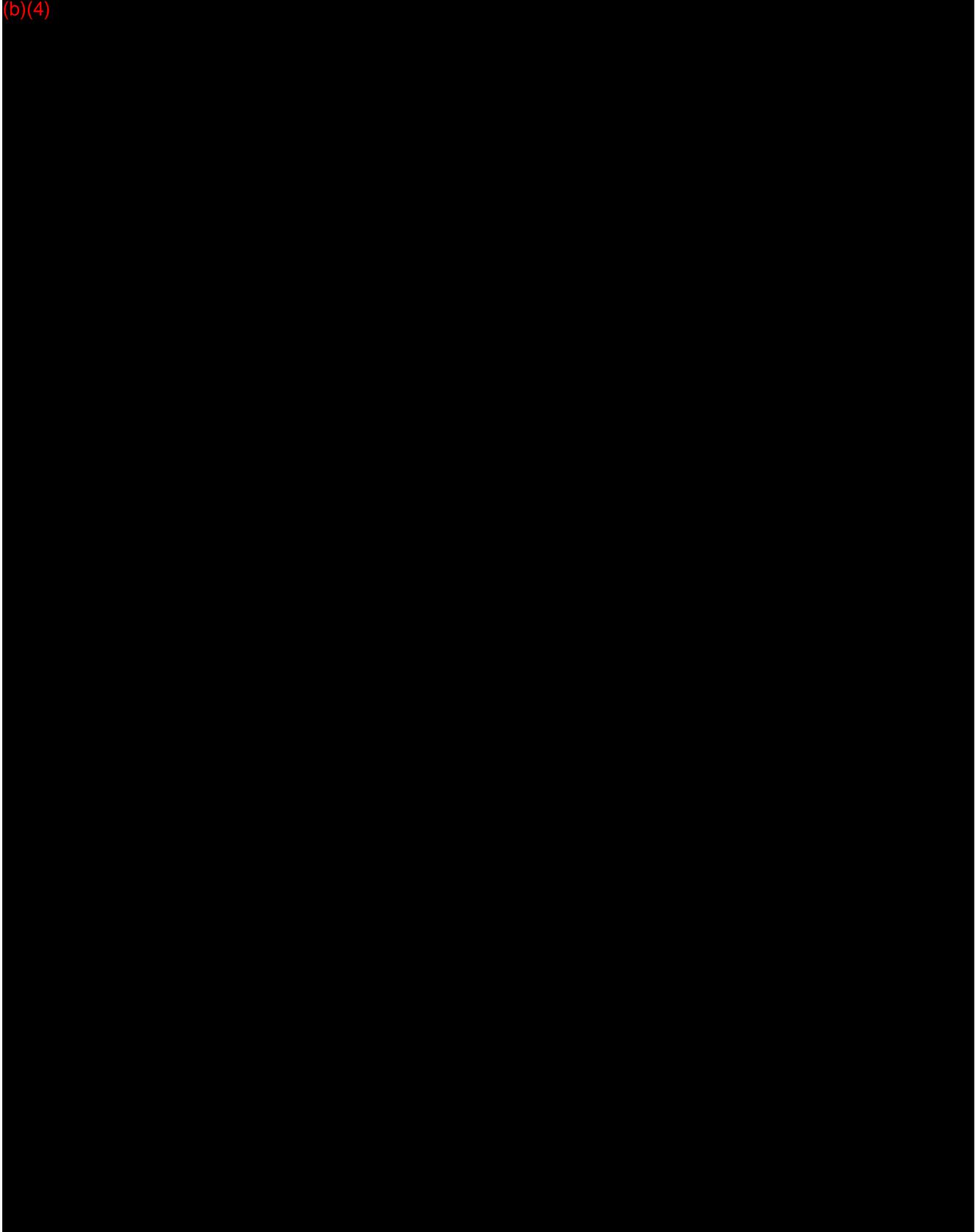


The performance of the CI strips was not affected by the presence of the possible contamination solutions tested.

A summary of the data is presented in **Table 18-9**.

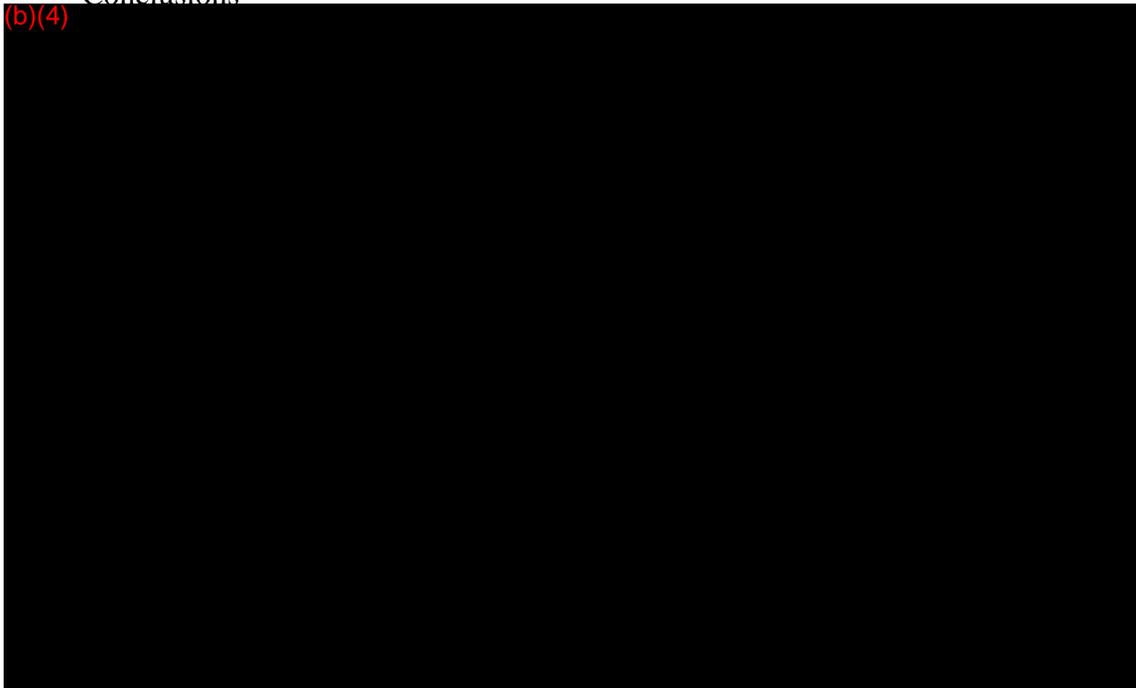
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Conclusions



The presence of possible contaminants from inadequate cleaning or rinsing of the medical devices does not affect the expected color change of CI strips processed in the SYSTEM 1E Processor.

Open Bottle Stability

It is the intention of STERIS Corporation to claim a 6 month shelf life for the Verify® SYSTEM 1E Chemical Indicator following opening of the bottle. This claim shall be based on real time stability data. STERIS does not yet have data based on the current test system to support the proposed open bottle stability claim. However, (b)(4), indicates that the Chemical Indicator will be stable following 13 months of opening the bottle. This testing, (b)(4) is detailed below and in **Appendix M** of this submission. These results will be further confirmed for the indicated open bottle stability time points as additional testing will be performed using the current methodologies as described in **Appendix A, Section 5.11**.

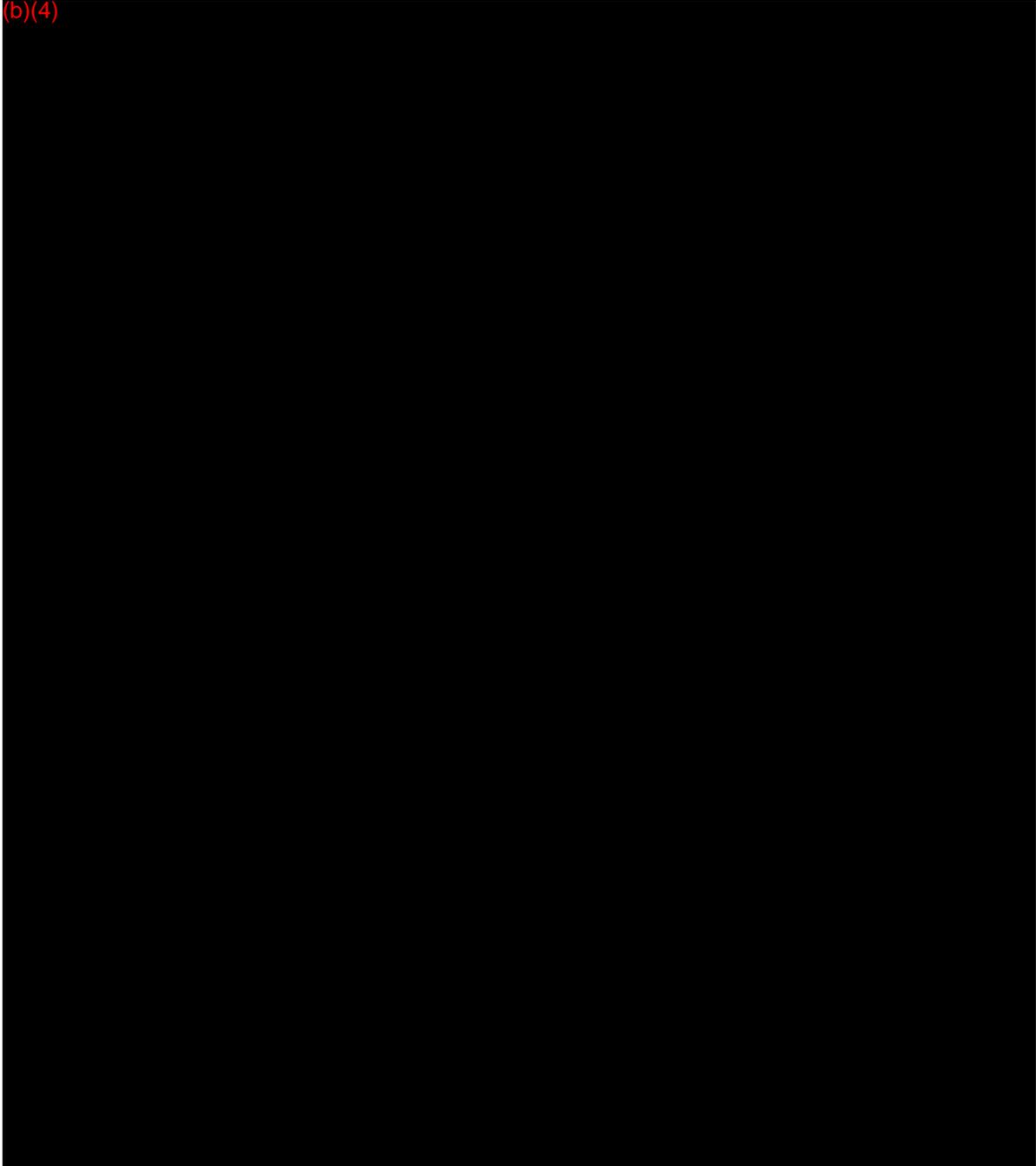
A promissory statement that STERIS will not make shelf-life claims or stability claims without having the supporting testing information is provided as **Appendix O**.

Test Objective

The objective of this testing was to monitor the performance of the proposed Verify® SYSTEM 1E Chemical Indicator during and after the 6 months of proposed in-use life after the bottle is opened.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)

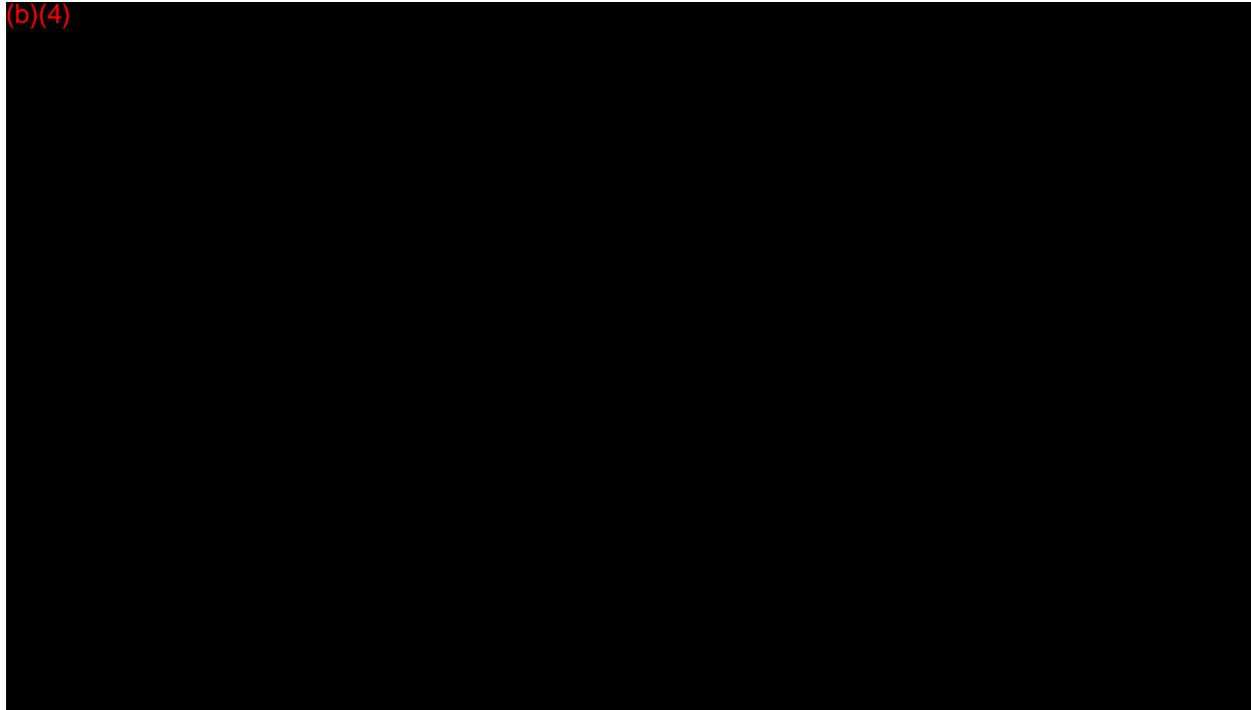


Results

Table 18-10 lists the indicator in-use shelf life testing cycles/exposures run to date with the proposed Verify[®] SYSTEM 1E Chemical Indicator.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

(b)(4)



Toxicity Analysis

The Verify[®] SYSTEM 1E Chemical Indicator does not contain components that come into direct or indirect contact with patients.

The Verify[®] SYSTEM 1E Chemical Indicator consists of reactive chemicals printed on one end of a polypropylene strip. A clear, sterilant-permeable polyether block amide laminate is adhesively bonded to the polypropylene strip following printing of the ink, completely covering the ink.

A Hazard Analysis for the proposed Verify[®] SYSTEM 1E Chemical Indicator is included in **Appendix N**.

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY[®] SYSTEM 1E CHEMICAL INDICATOR**

**Performance Testing - Animal
For
Verify[®] SYSTEM 1E Chemical Indicator**

This section does not apply.

Performance Testing - Clinical
For
Verify[®] SYSTEM 1E Chemical Indicator

This section does not apply.

APPENDIX A

Protocol 10028753 Verification of the Chemical Indicator for use in the STERIS SYSTEM 1E Liquid Chemical Sterilant Processor

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Protocol

10028753

**Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX B

Master Report 10028889 **Verification of the Chemical Indicator for use in the** **STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

**Master Report
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

10028889

In Support of Protocol 10028753

APPENDIX C

Comparative Sensitivity and Specificity Report 10028892

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 1, Comparative Sensitivity and Specificity

10028892

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX D

Color Read for Time Out of Processor Report 10028893

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 2, Color Read for Time Out of Processor

10028893

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX E

Color Read for Time before Removal from Processor Report 10028894

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

**Laboratory Report for Study 3, Color Read for Time before Removal
from Processor**

10028894

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX F

Analytic Specificity Report 10028865

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 4, Analytic Specificity

10028865

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX G

Blind Reader Evaluation Report 10028896

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 5, Blind Reader Evaluation

10028896

In Support of Protocol 10028753

**Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX H

Simulated Use Report 10028897

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 6, Simulated Use

10028897

In Support of Protocol 10028753

**Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX I

Exposure to UV Light Report 11028898

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 7, Exposure to UV Light

11028898

In Support of Protocol 10028753

**Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX J

Shelf Life Report 10028999

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 8, Shelf Life

10028999

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX K

Effects of Aggressive Chemicals Report 11028900

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 9, Effects of Aggressive Chemicals

11028900

In Support of Protocol 10028753

**Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

APPENDIX L

Effects of Contaminants Report 10028901

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

Released

**CONFIDENTIAL
STERIS CORPORATION**

Laboratory Report for Study 10, Effects of Contaminants

10028901

**In Support of Protocol 10028753
Verification of the Chemical Indicator for use in the
STERIS SYSTEM 1E Liquid Chemical Sterilant Processor**

APPENDIX M

In-Use Shelf Life

	Page
Standard Operating Procedure - SOP 13 Rev 3.....	M-2
Report - RDP.154SSL4, 5 & 6.....	M-6

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

APPENDIX N

SYSTEM 1E Chemical Indicator Risk Assessment

**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

APPENDIX O

Shelf Life Promissory Note

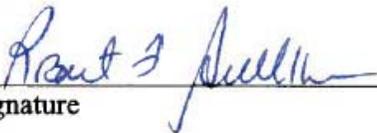
**STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
VERIFY® SYSTEM 1E CHEMICAL INDICATOR**

STERIS®



**Shelf Life Certification Statement
For the proposed
Verify® SYSTEM 1E Chemical Indicator**

I certify that, in my capacity as Senior Director, FDA Regulatory Affairs of STERIS Corporation, claims for shelf life stability for the proposed Verify® SYSTEM 1E Chemical Indicator will not be made until testing has been completed and satisfactory testing information obtained.



Signature

8/5/2010
Date

Robert Sullivan
Senior Director, FDA Regulatory Affairs



COVER SHEET MEMORANDUM

From: Reviewer Name Elaine S. Mayhall
Subject: 510(k) Number K102217/S3
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <=21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)			/
Nanotechnology			/
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact OC.	/

Regulation Number	Class	Product Code
880.2800	II	J0J

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: fr Susan Rimmer (Branch Chief) INCB (Branch Code) 11/22/10 (Date)

Final Review: [Signature] (Division Director) 11/22/10 (Date)
Deputy Division Director

5



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102217/S3

Date: November 22, 2010
To: The Record
From: Elaine S. Mayhall, Ph.D.

Office: ODE
Division: INCB/DAGID

510(k) Holder: Steris Corp.
Device Name: Verify System 1E Chemical Indicator
Contact: Robert F. Sullivan
Phone: 440-392-7695
Fax: 440-357-9198
Email: Rsullivan@steris.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Verify System 1E Chemical Indicator into interstate commerce. The indicator is specifically for use in the Steris System 1E Liquid Chemical Sterilant Processing System, cleared under K090036. (b)(4)

(b)(4)

In the current submission, the firm

provided their response to the 11/15/10 FDA request for additional information. Based on their responses, no additional information is needed and I recommend that the Verify System 1E Chemical Indicator be found SE.

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

Table with 4 columns: Requirement, YES, NO, N/A. Rows list required elements for 510(k) Summary such as 'Clearly labeled 510(k) Summary', 'Submitter's name, address, phone #, a contact person', etc.

7

		YES	NO	N/A
Technological characteristics	if same, a summary of comparison of technological characters	X		
	If different, a summary of how do they compare to the Predicate			X
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 			
	Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)				
	Signed verbatim statement			X

Comment: The firm should revise their Summary as indicated above. The firm will need to identify a new predicate because the SS1 CI cannot serve as a predicate.

S2 Response: The firm provided a revised Summary. However, they will be requested to revise the document per identification of a new predicate.

S3 Response: The firm provided an acceptable revised 510(k) Summary.

III. Device Description

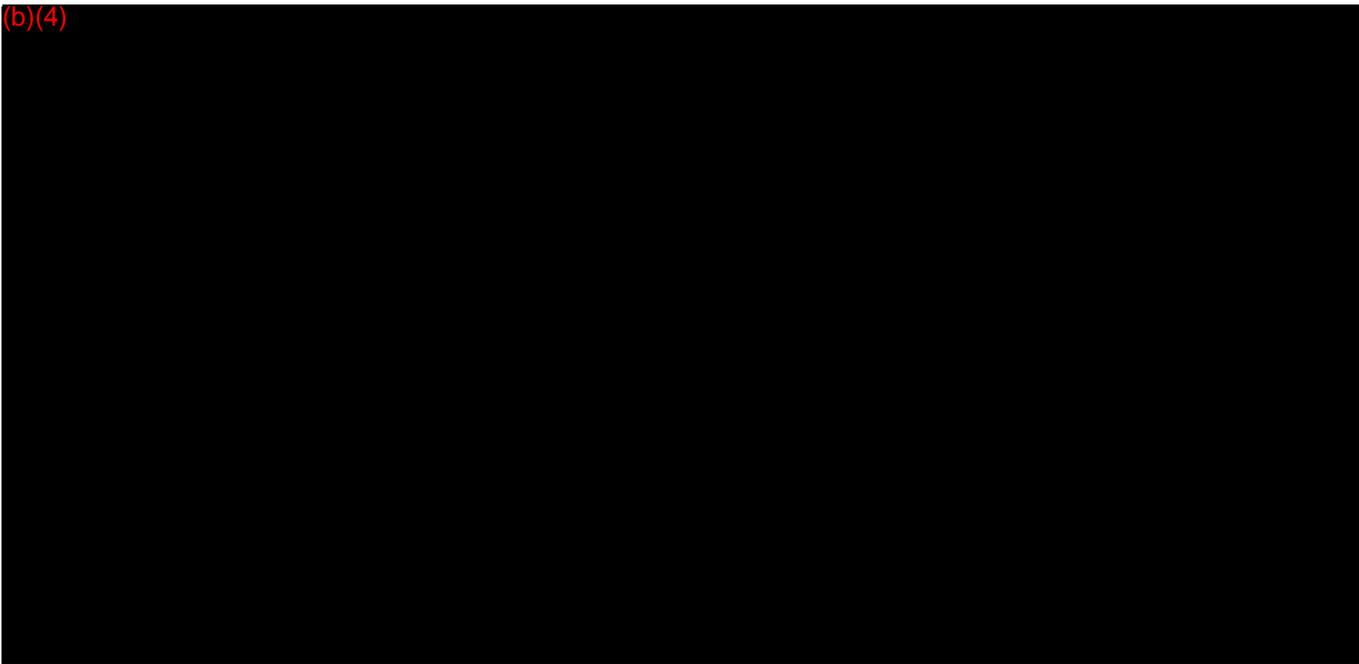
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Verify® System 1E Chemical Indicator (SS1E CI) is a single use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant permeable laminate made of polyether amide to protect the strip from damage during handling and prevent the indicator ink from leaching from the substrate. It 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 Sterilization System* processor during a processing cycle. The CI is placed in the system by clipping it to the dedicated peg in the processor tray. The instructions direct the user to read the color within 30 min of the cycle completion.

The ink is screen printed onto the substrate. The polyether amide laminated then is adhesively bonded to the polypropylene strip, covering the ink. The strip measures 10 mm x 83 mm. The firm indicates that the

indicator spot undergoes a color change from blue to pink when exposed to a SS1E cycle using S40 Sterilant Concentrate at an in-use peracetic acid concentration of >1820 ppm (mg/L).

(b)(4)



The CIs are packaged non-sterile in an airtight polypropylene bottle containing a maximum of 60 indicators with an integral desiccant sleeve to absorb moisture and a snap-top lid. Two bottles are packed in a shipper box along with a clip and the instructions for use.

Comment: The Steris System 1E was cleared as the Steris System 1 E Liquid Chemical Sterilant Processing System for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. The firm should use this name consistently throughout the document to refer to the cleared system.

S2 Response: The firm acknowledged the advisement and documentation reflects the correct name.

IV. Indications for 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 a darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.

Comment: The firm's previous IFU (K092865) stated "When exposed to a concentration of >1800 ppm peracetic acid."

V. Predicate Device Comparison

The firm indicates that the predicate device for the Verify® System 1E Chemical Indicator is the Steris Verify Chemical Indicator for Steris System 1 Sterile Processing System, cleared as Verify SPI Chemical Indicator under K052535.

Comment: The consent decree (based on QSR violations) for the Steris System 1 Processor (SS1)

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demonstrated removal "at the initiative of the Secretary" under section 513(i)(2). Because the Steris Process Chemical Indicator was marketed as cleared, cleared only for use with the SS1, and removed from the market only upon FDA's demand and pursuant to a consent decree, it may no longer serve as a predicate device. Therefore, another predicate device should be identified. The Verify System 1 E Chemical Indicator is similar to other chemical indicators used with liquid chemical sterilants, such as the Serim® DISINTEK OPA Test Strips, which is a chemical indicator for use in determining whether the concentration of orthophthalaldehyde, the active ingredient in Cidex® OPA Solution, is above or below the minimum effective concentration (MEC) established for Cidex OPA Solution.

S2 Response: We do not believe that use of the Steris System 1 Chemical Indicator is appropriate as a predicate at this time. Therefore, the firm should be requested to identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.

S3 Response: The firm identified 2 predicate devices, the Verify Chemical Monitoring Strip for Resert Solutions, K081600, and the Reliance CI Process Indicator, K063285, and provided a new comparison table.

VI. Labeling

The firm provided the proposed labeling, which includes the intended use (indications for use) performance characteristics, instructions for use, storage conditions, expiration date, performance limitations, safety precautions, disposal instructions, and the name, address, and phone numbers of the manufacturer. The bottle label includes color blocks showing examples of the start, pass, and fail colors. The labeling uses the cleared name of the SS1E Processor. The labeling warns against use of the indicators by anyone with color blindness. The disposal instructions indicate that the product is free of lead and other heavy metals.

Comment: The firm should restate the disposal instructions to omit the reference to lead or other heavy metals or they should revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals.

Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), the firm should include statements in the labeling warning the user to carefully assess the color change and follow the instructions closely.

S2 Response: The firm revised the instructions for use to indicate that the product is manufactured without lead or other heavy metals. The firm's revision is acceptable. The firm provided revised instructions for use so that the user is alerted to carefully assess the color change as instructed. For example, the firm includes bolded instructions to the user to carefully assess the color change immediately or within 30 min of cycle completion and that as a Pass, the strip must reach a color the same as, or more pink than, the Pass reference color on the bottle label. The revisions are acceptable.

VII. Sterilization/Shelf Life/Reuse

Sterilization: Indicators are provided non-sterile.

Reuse: The indicators are single use only.

Storage Conditions: Store at 43-86°F (6-30°C) and 30-60% relative humidity in original, tightly sealed bottle away from direct light. Do not store near heat, moisture, strong acids/alkalis, detergents, or oxidizing agents. The firm states in the labeling that the indicators can not be used as a permanent record.

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Shelf life: The shelf life is 6 mos from the date opened or the printed expiration, whichever is shorter. Indicators expire the last day of the month printed on the label or 6 months after opening, whichever is first. The firm plans to claim a 24-month shelf life for the SS1E CI and provided a test protocol (App. A) for real time shelf life stability testing. However, testing to date, which the firm has provided in App. J, supports a 15-mo claim. The firm will limit their claim to 15 mos until testing to support a 24-mo claim has been successfully completed. The firm provided a promissory note in App. O indicating that they will not make shelf-life claims or stability claims without having the supporting testing information.

Open bottle: The firm provided the test results to date for open bottle testing in App. M per the protocol in App. A.

Comment: I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.

Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.

S1 Response: The firm provided the protocol for a new shelf life study and a promissory statement as requested. The firm also provide a 7-week interim report on a new opened bottle shelf life study and a promissory note as requested. See responses to 8/26/10 request below under Deficiencies.

VIII. Biocompatibility

The SS1E CIs do not have direct or indirect contact with patients. They do not contain lead or other heavy metals. However, the firm provided a Hazard Analysis/Risk Assessment in App. N.

IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

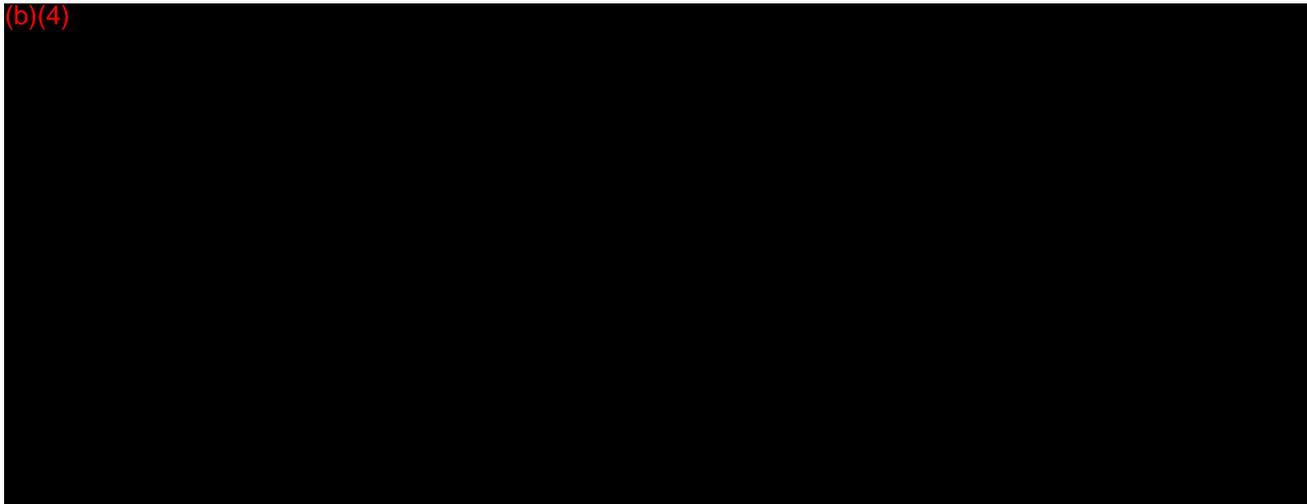
➤ (b)(4)

(b)(4) the indicator changes color from blue through an intermediate gray/green and then to the endpoint color beige. The indicator may become a lighter pink color when exposed to higher peracetic acid concentrations in S40 use dilution."

- In their current submission, the indications for use states, "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 darker pink when exposed to higher peracetic acid concentrations in S40 use dilution."
- In the performance testing in their previous submission, the firm showed ≥90% Pass at 1800 ppm

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(b)(4)



In the current submission, the firm evaluated the three lots of the Verify SS1E CI as follows. The PAA concentration at the start of exposure was monitored for all studies in which the CI was processed in the SS1E. For PAA analysis (b)(4)

(b)(4)

(b)(4)

Color

blocks showing color samples were provided in Section 11 page 4.

Summary of Performance Testing

Study	Purpose	Results	Conclusion
1	Comparative Sensitivity: Verify CI can accurately distinguish between Pass and Fail – 2 runs each under Pass and Fail conditions using 15 CIs per lot for total of 90 CIs per test condition	100% Pass (b)(4) ppm PAA w/ Pink color (b)(4) (b)(4) ppm PAA w/ beige color	CI performed per the acceptance criteria.
2	Determine time interval required within which user must interpret the color change results after removal from processor	Up to 60 min, 100% still indicated Pass. Up to 30 min, 100% still indicated Fail.	The time interval required to interpret the result is 30 min.
3	Determine time required within which user must interpret the color change results after delay in opening the processor	Up to 60 min delay, 100% still indicated Pass. Up to 30 min delay, 100% still indicated Fail.	The time limit for removal from the processor is 30 min.
4	Verify that color change in indicator is specific to PAA when used in the SS1E processor	100% fail when exposed to Builders only	The indicator does not react in the absence of PAA.
5	Verify that processed indicator color is interpreted correctly by readers unaware of PAA concentration	3 readers correctly evaluated all indicators; the instructions were: Pass is pink or more pink than Pass reference color block; Fail is less pink than Pass reference color block	Firm concluded that color change can be correctly interpreted. However, the firm provided no color samples; it appears that the fail and pass colors are very close; it appears that the readers were from the lab and were already familiar with the color change

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Study	Purpose	Results	Conclusion
6	Evaluate effects that placing an endoscope in processor container may have on performance of strip	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Addition of a device to the chamber does not affect the performance of the CI strip.
7	Determine if exposure to UV radiation has effect on Start color of unprocessed strips	Color change noted in unprocessed strips exposed to UV No color change noted in unprocessed strips stored in closed bottle.	CI strips should be kept in the closed bottle.
8	Determine performance of CI over shelf life storage time and conditions: 5°C 22°C/80% RH 31°C/60% RH	Testing at 15 mos storage showed 100% Pass at (b)(4) 100% Fail (b)(4) ppm PAA	CI is stable through 15 mos storage under low and high temp, and low and high humidity; firm provided protocol and promissory note for ongoing testing
9	Evaluate effects of aggressive chemicals on CI performance	Color change noted when CI strips in open bottle were stored near acidic and alkaline solutions.	CI strips should be kept in closed bottle.
10	Evaluate CI strip is affected by presence of contaminants , such as serum, saline and detergents.	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Contaminants do not affect the performance of the CI
11	Determine if performance of CI changes with time after bottle is opened	Firm indicates testing is ongoing. Results at 13 mos show failures. Firm limits opened bottle claim to 6 mos based on previous data.	Should limit claim to 3 mos until data available at 6 mos with current criteria; firm provided 7-wk interim data to support an opened bottle claim and promissory note to limit the claim to 3 mo until additional data are collected to support a longer claim.

Comments:

- It appears that the shelf life stability study is part of the ongoing shelf life stability testing that was also presented in the previous submission. However, for this interim report at 15 mos, the testing criteria were altered to meet the new Pass/Fail criteria. The shelf life stability testing is ongoing; the firm provided the protocol and a promissory note to complete the testing. Although, for the initial time points for the shelf stability study the CIs were evaluated per 90% Pass at 1800 ppm PAA and 100% Fail at 1200 ppm PAA, the data at 15 mos appear to demonstrate stability of the CI under the label storage conditions.
- The firm should provide a protocol for a new opened bottle study using the current color interpretation criteria and a promissory note that the claim will not be increased until testing supporting the claim has been completed.

S1 Response: The firm provided a protocol and promissory note as requested; see Deficiencies for

details.

- The firm did not provide testing to demonstrate the stability of the color change over time. The color does not remain stable; therefore, the firm instructs the user to read the change within 30 min of cycle completion.

XII. Performance Testing – Animal – Not Applicable

XIII. Performance Testing – Clinical – Not Applicable

XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?	X	If NO = Request Data
9. Data Demonstrate Equivalence?	X	Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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XV. Deficiencies

First Request – 8/25/10: In an email to Mr. Sullivan, I requested the following additional information:

- Please provide samples of the indicators showing the starting blue color, the fail gray/green and fail beige colors, and the pass pale pink color. It is unclear that the difference between beige and pale pink are easily distinguishable. For each indicator that is exposed to the System 1E process, please indicate the concentration of the peracetic acid that was measured during the exposure phase.
 - Dr. Kapil Panguluri (INCB) and I discussed this issue in a 1:00 pm teleconference with the firm (Mr. Sullivan, Marcia Benedict and others). The firm referred me to pages 11-3 and 11-4 for color samples. The color blocks on page 11-4 are the reference blocks used during testing and that will appear on the device label. FDA indicated that the firm should provide additional blind testing with readers that are not associated with Steris Corp. Testing should be conducted with (b)(4) to help better determine a user's ability to correctly interpret the color change, particularly under worst case conditions at the MRC of 1800 ppm to determine if the user can distinguish correctly between beige and pale pink. The S40 Sterilant solution is generated by dilution in the SS1E and is single use. (b)(4) Therefore, it should only be in limited situations when the user would be faced with reading this color difference. Testing presented in the 510(k) for the SS1E showed that the system reliably and predictably generates solution at the nominal concentration. In addition, labeling statements will be added to ensure that the user carefully interprets the color of the processed indicator.
 - In addition, I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.
 - Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.
- In an email dated **8/26/10**, I provided the firm with a summary of our discussion and requested the following information. The firm provided their S1 response as shown below.
 - a. Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (b)(4) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.

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S1 Response: The firm provided the report for a new study with 5 health care workers currently in device reprocessing as readers. The readers were not associated with Steris and were given instruction on reading the indicators. (b)(4)

(b)(4)

- b. Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol for a shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples will be stored under three different storage conditions and evaluated for physical characteristics and for color change following exposure in the (b)(4)

(b)(4)

40 strips per bottle from each of three lots will be evaluated at each time point over 2 years. The protocol appears to be adequate. The firm provided a promissory statement certifying that the firm will not extend the shelf life claim beyond 15 mos until real time data supporting the claim have been collected.

- c. Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol 7 week interim report for an opened bottle shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples were stored under three different storage conditions. The bottles were opened 3 times per week for 7 weeks. Unopened control bottles were stored similarly, but were only opened at the evaluation time point. (b)(4)

(b)(4)

(b)(4)

3 strips per bottle from each of three lots were evaluated at 7 weeks. The results showed that all test strips performed per the acceptance criteria. The firm provided a promissory statement certifying that the firm will not extend the opened bottle shelf life claim beyond 3 mos until real time data supporting the claim have been collected.

Third request – 11/8/10: In an email to to Mr. Sullivan, I requested the following additional information:

1. The Steris System 1E was cleared as the "Steris System 1 E Liquid Chemical Sterilant Processing System" for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. Please ensure that all final documentation, including your Indications for Use Statement, 510(k) Summary, and labeling, reflect the FDA-cleared name, Steris System 1 E Liquid Chemical Sterilant Processing System.

Response: The firm acknowledged the name and noted that they reviewed the proposed IFU statement, 510(k) Summary, and labeling to ensure they all reflect the cleared name. They also provided the revised instructions for use and 510(k) Summary, which contains the IFU, that use the name, "System 1 E Liquid Chemical Sterilant Processing System." The instructions for use and 510(k) Summary are acceptable.

2. In your labeling for the subject device, please restate the disposal instructions to omit the reference to lead or other heavy metals. Alternatively, please revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals. This recommendation is based on the fact that demonstrating that the indicators are "free" of lead or other heavy metals is not possible using current analytical methods.

Response: The firm revised the instructions for use to indicate that the product is manufactured without lead or other heavy metals. The firm's revision is acceptable.

3. Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), please add statements to the labeling warning the user to carefully assess the color change and to carefully follow the instructions.

Response: The firm provided revised instructions for use so that the user is alerted to carefully assess the color change as instructed. For example, the firm includes bolded instructions to the user to carefully assess the color change immediately or within 30 min of cycle completion and that as a Pass, the strip must reach a color the same as, or more pink than, the Pass reference color on the bottle label. The revisions are acceptable.

4. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary located under Tab 5 of your submission, FDA believes that your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:

- a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
- b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.
- c. Please include a summary of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria (if applicable) and intended uses.
- d. Please provide a conclusion statement that summarizes the data to demonstrate Substantial Equivalence.

Response: The firm provided a revised 510(k) Summary, which is acceptable, except that the predicate and predicate information should be revised to reflect a predicate other than the SS1 CI.

Final Request – 11/15/10: The firm should be requested to use a different predicate, such as the Steris Resert XL Test Strip and provide a new comparison to the predicate and a revised 510(k) Summary that reflects the new predicate. We do not believe that use of the Steris System 1 Chemical Indicator is appropriate as a predicate at this time.

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1. Please identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.

Response: The firm identified 2 predicate devices, the Verify Chemical Monitoring Strip for Resert Solutions, K081600, and the Reliance CI Process Indicator, K063285, and provided a new comparison table.

2. Please provide a new 510(k) Summary that reflects the new predicate. The revised 510(k) summary should reflect the new predicate name and:
 - a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
 - b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.

Response: The firm provided a new 510(k) Summary that has been revised as requested.

XVI. Contact History

08/25/10: Email request for information and Teleconference with firm

08/26/10: Email request to firm and document placed on hold

11/08/10: Email request for additional information and document palced on HOLD

11/15/10: Email request for additional information and document palced on HOLD

- XVII. Recommendation:** I recommend that the document, K102217, be found Substantially Equivalent to the predicate devices, the Verify Chemical Monitoring Strip for Resert Solutions, K081600, and the Reliance CI Process Indicator, K063285.

Regulation Number: 21 CFR 880.2800

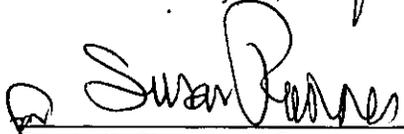
Regulation Name: Physical/chemical sterilization process indicator

Regulatory Class: Class II

Product Code: JOJ


Elaine Schalk Mayhall, Ph.D.

11/22/10
Date


Elizabeth Claverie, M.S.

11/22/10
Date



COVER SHEET MEMORANDUM

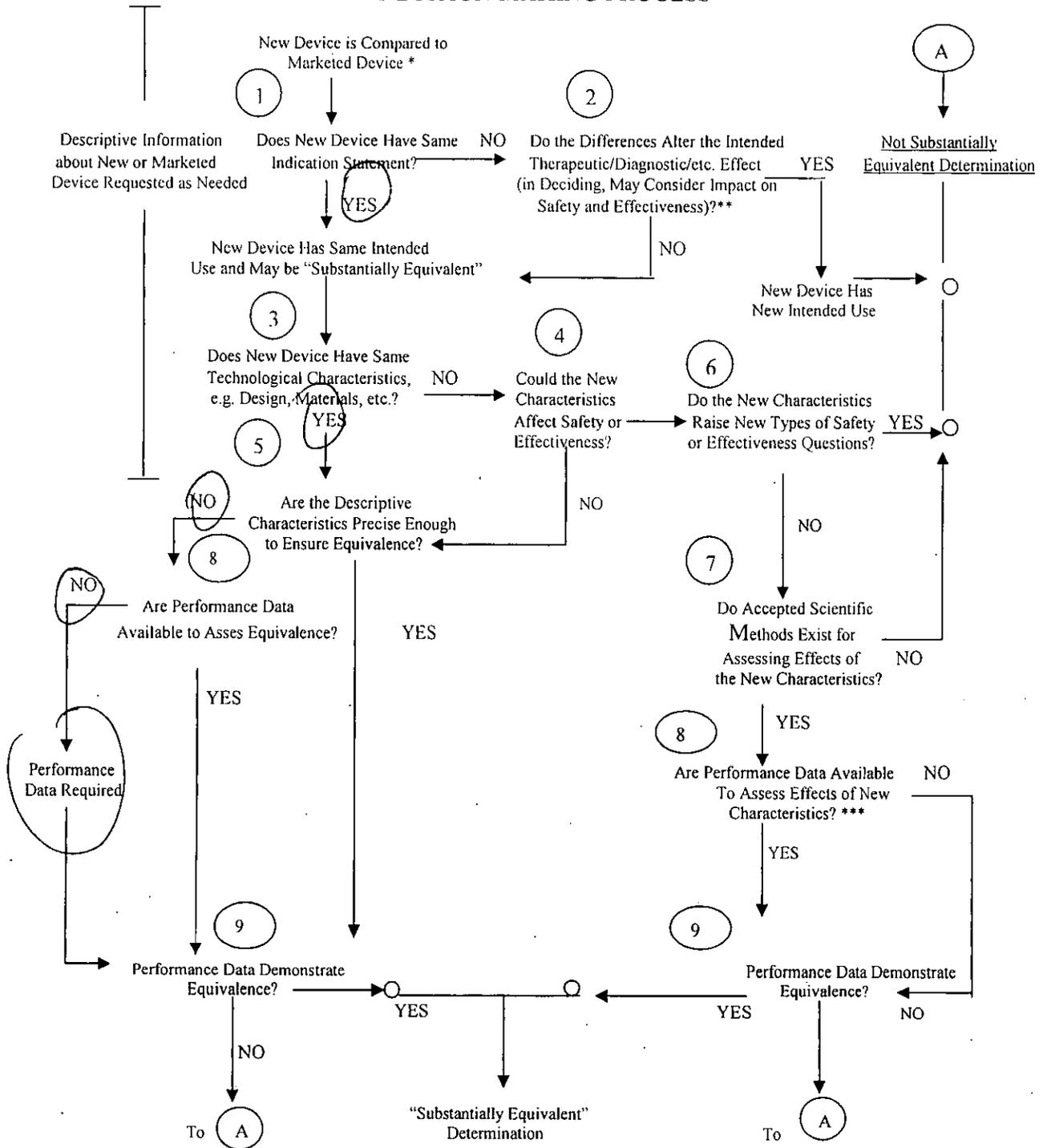
From: Reviewer Name Elaine Schalk, Mayhall
Subject: 510(k) Number K162217/52
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102217/S2

Date: November 15, 2010
To: The Record
From: Elaine S. Mayhall, Ph.D.

Office: ODE
Division: INCB/DAGID

510(k) Holder: Steris Corp.
Device Name: Verify System 1E Chemical Indicator
Contact: Robert F. Sullivan
Phone: 440-392-7695
Fax: 440-357-9198
Email: Rsullivan@steris.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Verify System 1E Chemical Indicator into interstate commerce. The indicator is specifically for use in the Steris System 1E Liquid Chemical Sterilant Processing System, cleared under K090036. This device previously (b)(4) data. In the current submission, the firm provided their response to the 11/8/10 FDA request for additional information.

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form - No standards were cited.

Table with 4 columns: Requirement, YES, NO, N/A. Rows include Required Elements for 510(k) Summary (21 CFR 807.92) such as Clearly labeled '510(k) Summary', Submitter's name, address, phone #, a contact person, Date the summary was prepared, The name of the device/trade name/common name/classification name, An identification of the legally marketed Predicate, Description of the subject device, and Statement of intended use.

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		YES	NO	N/A
Technological characteristics	if same, a summary of comparison of technological characters		X	
	If different, a summary of how do they compare to the Predicate		X	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 			
	Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)				
Signed verbatim statement				

Comment: The firm should revise their Summary as indicated above. The firm will need to identify a new predicate because the SS1 CI cannot serve as a predicate.

S2 Response: The firm provided a revised Summary. However, they will be requested to revise the document per identification of a new predicate.

III. Device Description

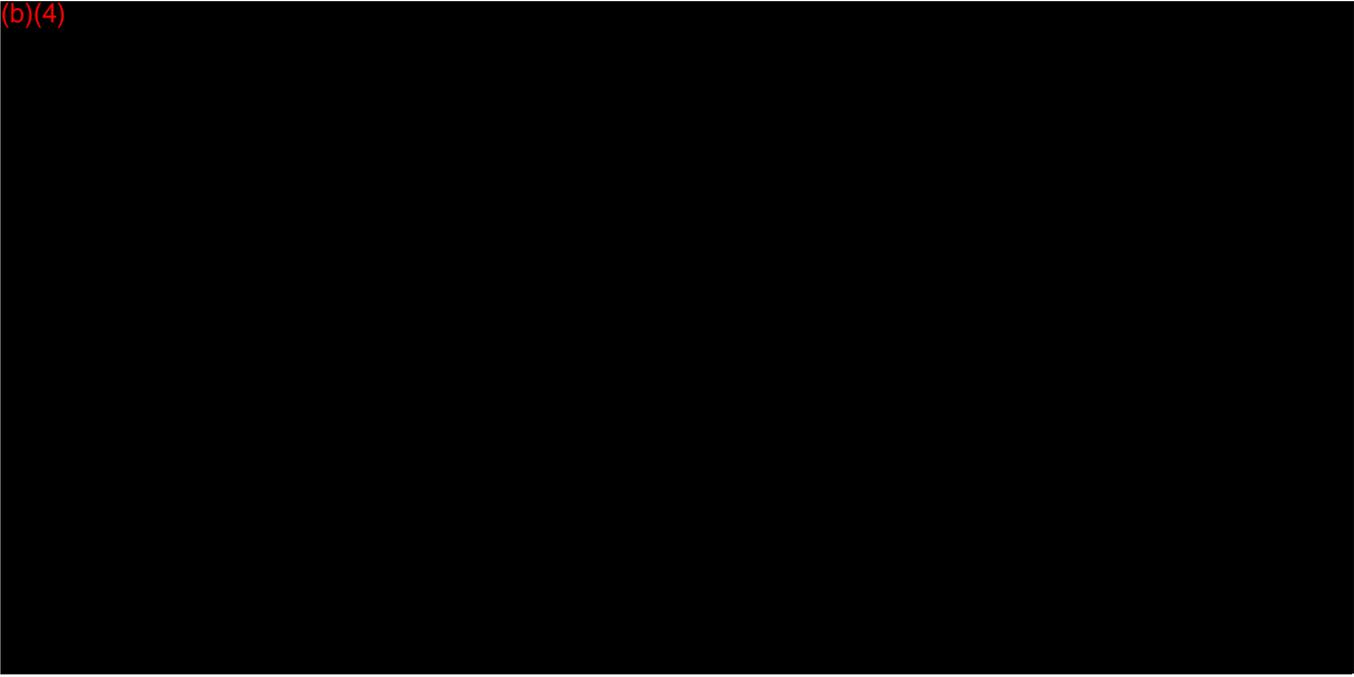
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Verify® System 1E Chemical Indicator (SS1E CI) is a single use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant permeable laminate made of polyether amide to protect the strip from damage during handling and prevent the indicator ink from leaching from the substrate. It 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 Sterilization System* processor during a processing cycle. The CI is placed in the system by clipping it to the dedicated peg in the processor tray. The instructions direct the user to read the color within 30 min of the cycle completion.

The ink is screen printed onto the substrate. The polyether amide laminated then is adhesively bonded to the polypropylene strip, covering the ink. The strip measures 10 mm x 83 mm. The firm indicates that the indicator spot undergoes a color change from blue to pink when exposed to a SS1E cycle using S40 Sterilant Concentrate at an in-use peracetic acid concentration of >1820 ppm (mg/L).

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(b)(4)



The CIs are packaged non-sterile in an airtight polypropylene bottle containing a maximum of 60 indicators with an integral desiccant sleeve to absorb moisture and a snap-top lid. Two bottles are packed in a shipper box along with a clip and the instructions for use.

Comment: The Steris System 1E was cleared as the Steris System 1 E Liquid Chemical Sterilant Processing System for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. The firm should use this name consistently throughout the document to refer to the cleared system.

S2 Response: The firm acknowledged the advisement and documentation reflects the correct name.

IV. Indications for 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 a darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.

Comment: (b)(4)

(b)(4)

V. Predicate Device Comparison

The firm indicates that the predicate device for the Verify® System 1E Chemical Indicator is the Steris Verify Chemical Indicator for Steris System 1 Sterile Processing System, cleared as Verify SPI Chemical Indicator under K052535.

Comment: The consent decree (based on QSR violations) for the Steris System 1 Processor (SS1) demonstrated removal "at the initiative of the Secretary" under section 513(i)(2). Because the Steris Process Chemical Indicator was marketed as cleared, cleared only for use with the SS1, and

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removed from the market only upon FDA's demand and pursuant to a consent decree, it may no longer serve as a predicate device. Therefore, another predicate device should be identified. The Verify System 1 E Chemical Indicator is similar to other chemical indicators used with liquid chemical sterilants, such as the Serim® DISINTEK OPA Test Strips, which is a chemical indicator for use in determining whether the concentration of orthophthalaldehyde, the active ingredient in Cidex® OPA Solution, is above or below the minimum effective concentration (MEC) established for Cidex OPA Solution.

S2 Response: We do not believe that use of the Steris System 1 Chemical Indicator is appropriate as a predicate at this time. Therefore, the firm should be requested to identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.

VI. Labeling

The firm provided the proposed labeling, which includes the intended use (indications for use) performance characteristics, instructions for use, storage conditions, expiration date, performance limitations, safety precautions, disposal instructions, and the name, address, and phone numbers of the manufacturer. The bottle label includes color blocks showing examples of the start, pass, and fail colors. The labeling uses the cleared name of the SS1E Processor. The labeling warns against use of the indicators by anyone with color blindness. The disposal instructions indicate that the product is free of lead and other heavy metals.

Comment: The firm should restate the disposal instructions to omit the reference to lead or other heavy metals or they should revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals.

Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), the firm should include statements in the labeling warning the user to carefully assess the color change and follow the instructions closely.

S2 Response: The firm revised the instructions for use to indicate that the product is manufactured without lead or other heavy metals. The firm's revision is acceptable. The firm provided revised instructions for use so that the user is alerted to carefully assess the color change as instructed. For example, the firm includes bolded instructions to the user to carefully assess the color change immediately or within 30 min of cycle completion and that as a Pass, the strip must reach a color the same as, or more pink than, the Pass reference color on the bottle label. The revisions are acceptable.

VII. Sterilization/Shelf Life/Reuse

Sterilization: Indicators are provided non-sterile.

Reuse: The indicators are single use only.

Storage Conditions: Store at 43-86°F (6-30°C) and 30-60% relative humidity in original, tightly sealed bottle away from direct light. Do not store near heat, moisture, strong acids/alkalis, detergents, or oxidizing agents. The firm states in the labeling that the indicators can not be used as a permanent record.

Shelf life: The shelf life is 6 mos from the date opened or the printed expiration, whichever is shorter. Indicators expire the last day of the month printed on the label or 6 months after opening, whichever is first. The firm plans to claim a 24-month shelf life for the SS1E CI and provided a test protocol (App. A) for real time shelf life stability testing. However, testing to date, which the firm has provided in App. J, supports a 15-mo claim. The firm will limit their claim to 15 mos until testing to support a 24-mo claim has been successfully completed. The firm provided a promissory note in App. O

indicating that they will not make shelf-life claims or stability claims without having the supporting testing information.

Open bottle: The firm provided the test results to date for open bottle testing in App. M per the protocol in App. A.

Comment: I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.

Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life, expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.

S1 Response: The firm provided the protocol for a new shelf life study and a promissory statement as requested. The firm also provide a 7-week interim report on a new opened bottle shelf life study and a promissory note as requested. See responses to 8/26/10 request below under Deficiencies.

VIII. Biocompatibility

The SS1E CIs do not have direct or indirect contact with patients. They do not contain lead or other heavy metals. However, the firm provided a Hazard Analysis/Risk Assessment in App. N.

IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

➤ (b)(4)

(b)(4) The indicator may become a lighter pink color when exposed to higher peracetic acid concentrations in S40 use dilution.”

- In their current submission, the indications for use states, “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 darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.”
- In the performance testing in their previous submission, the firm showed ≥90% Pass at 1800 ppm PAA with beige color and 100% Fail at 1200 ppm PAA with gray/green or blue color. In response, FDA indicated that 1200 ppm PAA was too low of a fail condition to support the performance of the indicator.

➤ In their current submission, the firm indicates that the Pass/Fail criteria are now ≥90% Pass at (b)(4) with a beige color.

(b)(4)

In the current submission, the firm evaluated the three lots of the Verify SS1E CI as follows. The PAA concentration at the start of exposure was monitored for all studies in which the CI was processed in the SS1E. For PAA analysis, samples were (b)(4)

(b)(4)

(b)(4)

for Fail testing conditions. Color blocks showing color samples were provided in Section 11 page 4.

Summary of Performance Testing

Study	Purpose	Results	Conclusion
1	Comparative Sensitivity: Verify CI can accurately distinguish between Pass and Fail – 2 runs each under Pass and Fail conditions using 15 CIs per lot for total of 90 CIs per test condition	100% Pass (b)(4) ppm PAA w/ Pink color 100% Fail (b)(4) ppm PAA w/ beige color	CI performed per the acceptance criteria.
2	Determine time interval required within which user must interpret the color change results after removal from processor	Up to 60 min, 100% still indicated Pass. Up to 30 min, 100% still indicated Fail.	The time interval required to interpret the result is 30 min.
3	Determine time required within which user must interpret the color change results after delay in opening the processor	Up to 60 min delay, 100% still indicated Pass. Up to 30 min delay, 100% still indicated Fail.	The time limit for removal from the processor is 30 min.
4	Verify that color change in indicator is specific to PAA when used in the SS1E processor	100% fail when exposed to Builders only	The indicator does not react in the absence of PAA.
5	Verify that processed indicator color is interpreted correctly by readers unaware of PAA concentration	3 readers correctly evaluated all indicators; the instructions were: Pass is pink or more pink than Pass reference color block; Fail is less pink than Pass reference color block	Firm concluded that color change can be correctly interpreted. However, the firm provided no color samples; it appears that the fail and pass colors are very close; it appears that the readers were from the lab and were already familiar with the color change
6	Evaluate effects that placing an endoscope in processor container may have on performance of strip	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Addition of a device to the chamber does not affect the performance of the CI strip.
7	Determine if exposure to UV radiation has effect on Start color	Color change noted in unprocessed strips	CI strips should be kept in the closed bottle.

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Study	Purpose	Results	Conclusion
	of unprocessed strips	exposed to UV No color change noted in unprocessed strips stored in closed bottle.	
8	Determine performance of CI over shelf life storage time and conditions: 5°C 22°C/80% RH 31°C/60% RH	Testing at 15 mos storage showed 100% Pass at (b)(4) (b)(4) (b)(4)	CI is stable through 15 mos storage under low and high temp, and low and high humidity; firm provided protocol and promissory note for ongoing testing
9	Evaluate effects of aggressive chemicals on CI performance	Color change noted when CI strips in open bottle were stored near acidic and alkaline solutions.	CI strips should be kept in closed bottle.
10	Evaluate CI strip is affected by presence of contaminants , such as serum, saline and detergents.	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Contaminants do not affect the performance of the CI
11	Determine if performance of CI changes with time after bottle is opened	Firm indicates testing is ongoing. Results at 13 mos show failures. Firm limits opened bottle claim to 6 mos based on previous data.	Should limit claim to 3 mos until data available at 6 mos with current criteria; firm provided 7-wk interim data to support an opened bottle claim and promissory note to limit the claim to 3 mo until additional data are collected to support a longer claim.

Comments:

- It appears that the shelf life stability study is part of the ongoing shelf life stability testing that was also presented in the previous submission. However, for this interim report at 15 mos, the testing criteria were altered to meet the new Pass/Fail criteria. The shelf life stability testing is ongoing; the firm provided the protocol and a promissory note to complete the testing. Although, for the initial time points for the shelf stability study the CIs were evaluated per 90% Pass at 1800 ppm PAA and 100% Fail at 1200 ppm PAA, the data at 15 mos appear to demonstrate stability of the CI under the label storage conditions.
- The firm should provide a protocol for a new opened bottle study using the current color interpretation criteria and a promissory note that the claim will not be increased until testing supporting the claim has been completed.

S1 Response: The firm provided a protocol and promissory note as requested; see Deficiencies for details.

- The firm did not provide testing to demonstrate the stability of the color change over time. The color does not remain stable; therefore, the firm instructs the user to read the change within 30 min of cycle completion.

XII. Performance Testing – Animal – Not Applicable

XIII. Performance Testing – Clinical – Not Applicable

XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

First Request – 8/25/10: In an email to Mr. Sullivan, I requested the following additional information:

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- Please provide samples of the indicators showing the starting blue color, the fail gray/green and fail beige colors, and the pass pale pink color. It is unclear that the difference between beige and pale pink are easily distinguishable. For each indicator that is exposed to the System 1E process, please indicate the concentration of the peracetic acid that was measured during the exposure phase.
 - Dr. Kapil Panguluri (INCB) and I discussed this issue in a 1:00 pm teleconference with the firm (Mr. Sullivan, Marcia Benedict and others). The firm referred me to pages 11-3 and 11-4 for color samples. The color blocks on page 11-4 are the reference blocks used during testing and that will appear on the device label. FDA indicated that the firm should provide additional blind testing with readers that are not associated with Steris Corp. Testing should be conducted with (b)(4) help better determine a user's ability to correctly interpret the color change, particularly under worst case conditions at the MRC of 1800 ppm to determine if the user can distinguish correctly between beige and pale pink. The S40 Sterilant solution is generated by dilution in the SS1E and is single use. (b)(4). Therefore, it should only be in limited situations when the user would be faced with reading this color difference. Testing presented in the 510(k) for the SS1E showed that the system reliably and predictably generates solution at the nominal concentration. In addition, labeling statements will be added to ensure that the user carefully interprets the color of the processed indicator.
 - In addition, I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.
 - Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.
- In an email dated 8/26/10, I provided the firm with a summary of our discussion and requested the following information. The firm provided their S1 response as shown below.
 - a. Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (b)(4) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.

S1 Response: The firm provided the report for a new study with 5 health care workers currently in device reprocessing as readers. The readers were not associated with Steris and were given instruction on reading the indicators. (b)(4)

(b)(4) The test was repeated with another set of CIs. (b)(4)
The test was repeated with another set of CIs. Therefore, 90 CIs were processed per

condition. The readers were blind to the processing conditions. The CIs were randomly numbered. All CIs were read within 30 min of processing. The results showed that all CIs processed (b)(4) were read as Fail (less pink than the pass reference color block).

- b. Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol for a shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples will be stored under three different storage conditions and evaluated for physical

(b)(4)
(b)(4) 40 strips per bottle from each of three lots will be evaluated at each time point over 2 years. The protocol appears to be adequate. The firm provided a promissory statement certifying that the firm will not extend the shelf life claim beyond 15 mos until real time data supporting the claim have been collected.

- c. Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol 7 week interim report for an opened bottle shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples were stored under three different storage conditions. The bottles were opened 3 times per week for 7 weeks. Unopened control bottles were stored similarly, but were only opened at the evaluation time point. The CIs were evaluated for color change following exposure in the SS1E to Pass conditions (b)(4)

(b)(4) 3 strips per bottle from each of three lots were evaluated at 7 weeks. The results showed that all test strips performed per the acceptance criteria. The firm provided a promissory statement certifying that the firm will not extend the opened bottle shelf life claim beyond 3 mos until real time data supporting the claim have been collected.

Third request – 11/8/10: In an email to to Mr. Sullivan, I requested the following additional information:

1. The Steris System 1E was cleared as the "Steris System 1 E Liquid Chemical Sterilant Processing System" for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. Please ensure that all final documentation, including your indications for Use Statement, 510(k) Summary, and labeling, reflect the FDA-cleared name, Steris System 1 E Liquid Chemical Sterilant Processing System.

Response: The firm acknowledged the name and noted that they reviewed the proposed IFU statement, 510(k) Summary, and labeling to ensure they all reflect the cleared name. They also provided the revised instructions for use and 510(k) Summary, which contains the IFU, that use the name, "System 1 E Liquid Chemical Sterilant Processing System." The instructions for use and 510(k) Summary are acceptable.

2. In your labeling for the subject device, please restate the disposal instructions to omit the reference to lead or other heavy metals. Alternatively, please revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals. This recommendation is based on the fact that demonstrating that the indicators are "free" of lead or other heavy metals is not possible using current analytical methods.

Response: The firm revised the instructions for use to indicate that the product is manufactured without lead or other heavy metals. The firm's revision is acceptable.

3. Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), please add statements to the labeling warning the user to carefully assess the color change and to carefully follow the instructions.

Response: The firm provided revised instructions for use so that the user is alerted to carefully assess the color change as instructed. For example, the firm includes bolded instructions to the user to carefully assess the color change immediately or within 30 min of cycle completion and that as a Pass, the strip must reach a color the same as, or more pink than, the Pass reference color on the bottle label. The revisions are acceptable.

4. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary located under Tab 5 of your submission, FDA believes that your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:

- a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
- b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.
- c. Please include a summary of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria (if applicable) and intended uses.
- d. Please provide a conclusion statement that summarizes the data to demonstrate Substantial Equivalence.

Response: The firm provided a revised 510(k) Summary, which is acceptable, except that the predicate and predicate information should be revised to reflect a predicate other than the SS1 CI.

Final Request – 11/15/10: The firm should be requested to use a different predicate, such as the Steris Resert XL Test Strip and provide a new comparison to the predicate and a revised 510(k) Summary that reflects the new predicate. We do not believe that use of the Steris System 1 Chemical Indicator is appropriate as a predicate at this time.

1. Please identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.
2. Please provide a new 510(k) Summary that reflects the new predicate. The revised 510(k) summary should reflect the new predicate name and:

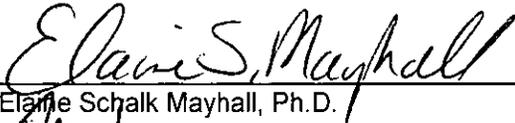
- a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
- b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.

XVI. Contact History

08/25/10: Email request for information and Teleconference with firm
08/26/10: Email request to firm and document placed on hold
11/08/10: Email request for additional information and document palced on HOLD
11/15/10: Email request for additional information and document palced on HOLD

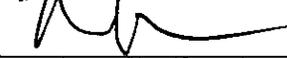
XVII. Recommendation: I recommend that the document, K102217, be placed ON PHONE HOLD pending receipt of the above additional information.

Regulation Number: 21 CFR 880.2800
Regulation Name: Physical/chemical sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ



Elaine Schalk Mayhall, Ph.D.

11/15/10
Date



Elizabeth Claverie, M.S.

11/16/10
Date

Mayhall, Elaine

From: Mayhall, Elaine
Sent: Monday, November 15, 2010 4:11 PM
To: 'Sullivan, Robert'
Cc: Claverie, Elizabeth F; Ulmer, Kwame; Robotham, James
Subject: K102217 Verify System 1E CI - Request 11/15/10

Dear Mr. Sullivan:

I have received the additional information in response to our 11/08/10 request. We do not believe that the Steris System 1 Chemical Indicator is appropriate as a predicate at this time. However, we believe that another chemical indicator cleared for a liquid chemical sterilant would be an appropriate predicate. Therefore, please provide the following additional information:

1. Please identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.
2. Please provide a new 510(k) Summary that reflects the new predicate. The revised 510(k) summary should reflect the new predicate name and:
 - a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
 - b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.

If you have any questions, please contact me at 301-796-6301 or by email.

Sincerely,

*Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WO66 Room 2612
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-6301
elaine.mayhall@fda.hhs.gov*

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

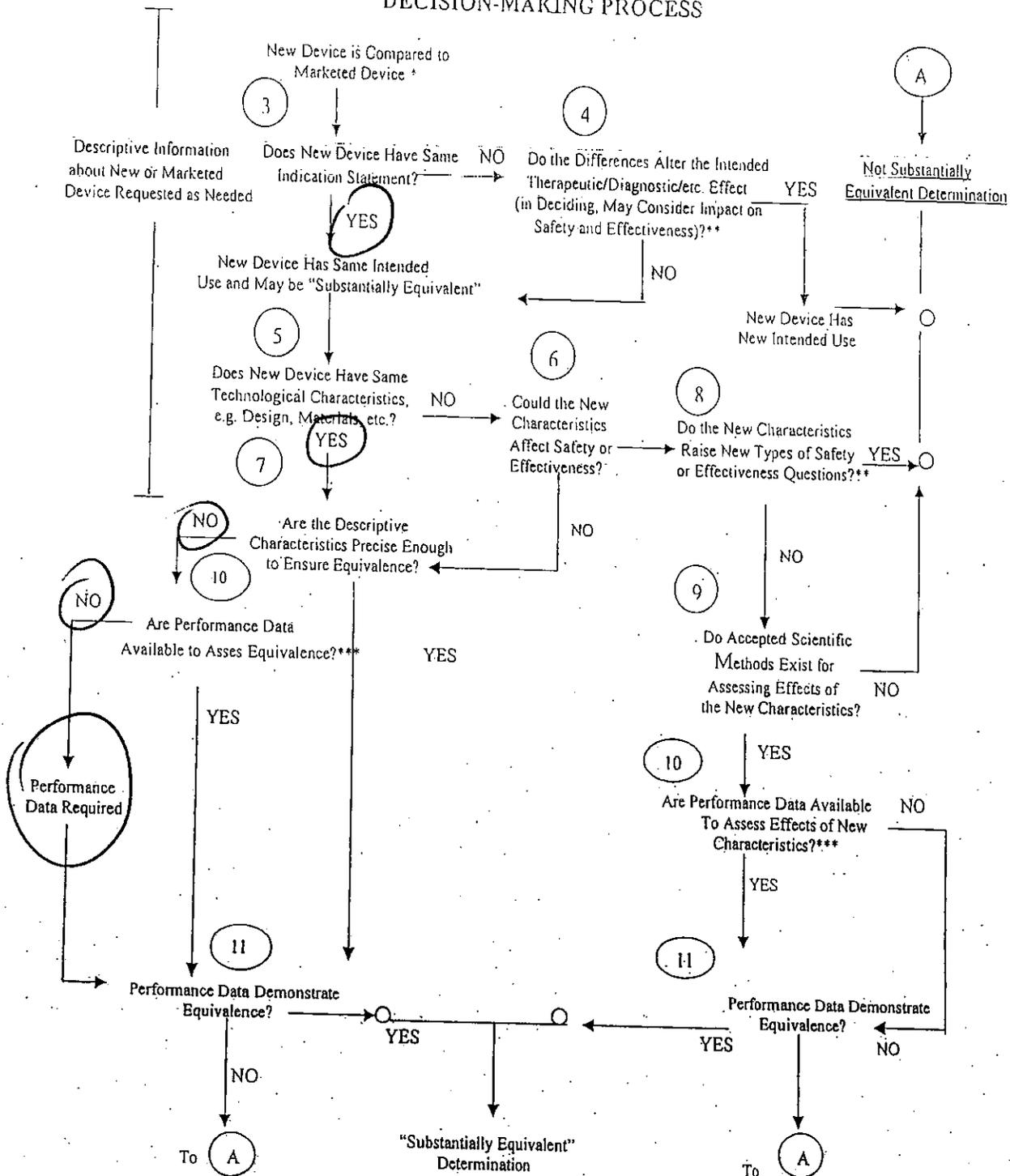
From: Reviewer Name Elaine Schalk Mayhall
Subject: 510(k) Number K102217/S1
To: The Record

- Please list CTS decision code TH
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data made in the 510(k) after 510(k) is the Center's classification of data on the device. Questions? Contact FDA/CDRH/CEMD at CDRH-FDAclassification@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102217/S1

Handwritten signature and date: 11/8/10

Date: November 8, 2010
To: The Record
From: Elaine S. Mayhall, Ph.D.

Office: ODE
Division: INCB/DAGID

510(k) Holder: Steris Corp.
Device Name: Verify System 1E Chemical Indicator
Contact: Robert F. Sullivan
Phone: 440-392-7695
Fax: 440-357-9198
Email: Rsullivan@steris.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Verify System 1E Chemical Indicator into interstate commerce. The indicator is specifically for use in the Steris System 1E Liquid Chemical Sterilant Processing System, cleared under K090036. This device previously was submitted under K092865 and subsequently found NSE due to lack of performance data. In the current submission, the firm provided their response to the 8/26/10 FDA request for additional information.

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

Table with 4 columns: Requirement, YES, NO, N/A. Rows include Required Elements for 510(k) Summary (21 CFR 807.92) such as Clearly labeled '510(k) Summary', Submitter's name, address, phone #, a contact person, Date the summary was prepared, The name of the device/trade name/common name/classification name, An identification of the legally marketed Predicate, Description of the subject device, and Statement of intended use.

Handwritten number 44

		YES	NO	N/A
Technological characteristics	if same, a summary of comparison of technological characters		X	
	If different, a summary of how do they compare to the Predicate		X	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 			
	Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)				
Signed verbatim statement				

Comment: The firm should revise their Summary as indicated above. The firm will need to identify a new predicate because the SS1 CI cannot serve as a predicate.

III. Device Description

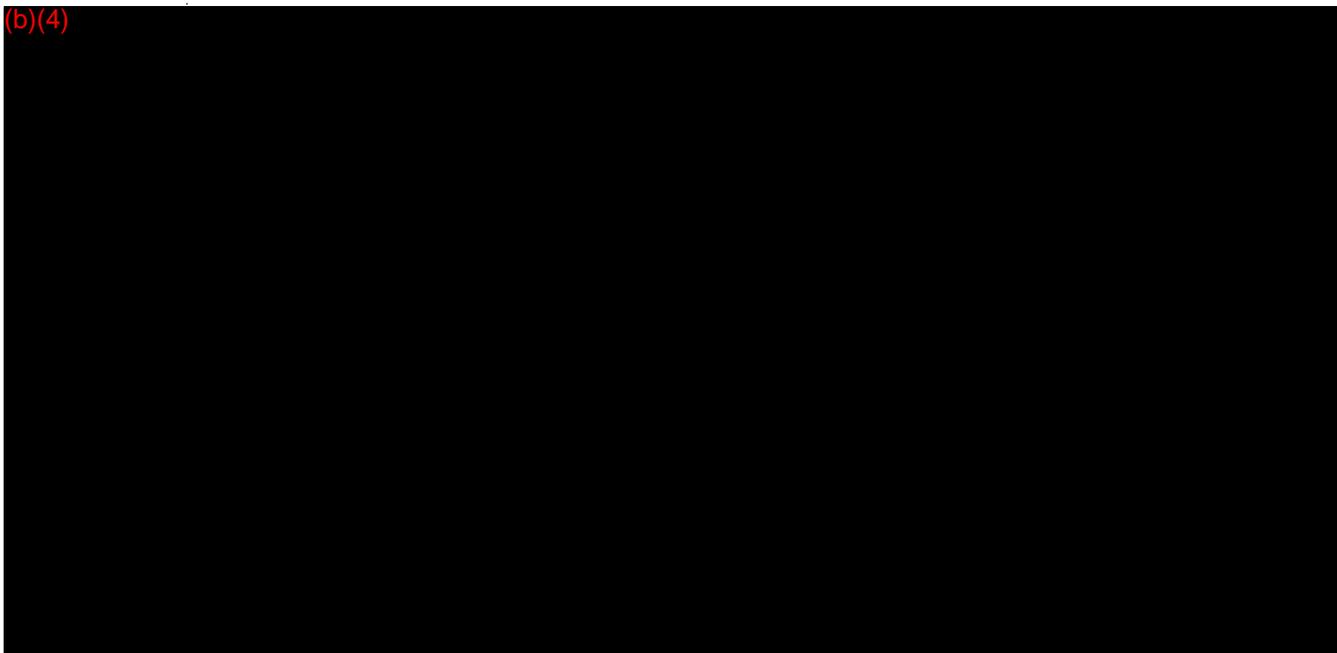
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Verify® System 1E Chemical Indicator (SS1E CI) is a single use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant permeable laminate made of polyether amide to protect the strip from damage during handling and prevent the indicator ink from leaching from the substrate. It 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 Sterilization System* processor during a processing cycle. The CI is placed in the system by clipping it to the dedicated peg in the processor tray. The instructions direct the user to read the color within 30 min of the cycle completion.

The ink is screen printed onto the substrate. The polyether amide laminated then is adhesively bonded to the polypropylene strip, covering the ink. The strip measures 10 mm x 83 mm. The firm indicates that the indicator spot undergoes a color change from blue to pink when exposed to a SS1E cycle using S40 Sterilant Concentrate at an in-use peracetic acid concentration of >1820 ppm (mg/L).

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(b)(4)



The CIs are packaged non-sterile in an airtight polypropylene bottle containing a maximum of 60 indicators with an integral desiccant sleeve to absorb moisture and a snap-top lid. Two bottles are packed in a shipper box along with a clip and the instructions for use.

Comment: The Steris System 1E was cleared as the Steris System 1 E Liquid Chemical Sterilant Processing System for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. The firm should use this name consistently throughout the document to refer to the cleared system.

IV. Indications for 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 a darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.

Comment: (b)(4)

(b)(4)

V. Predicate Device Comparison

The firm indicates that the predicate device for the Verify® System 1E Chemical Indicator is the Steris Verify Chemical Indicator for Steris System 1 Sterile Processing System, cleared as Verify SPI Chemical Indicator under K052535.

Comment: The consent decree (based on QSR violations) for the Steris System 1 Processor (SS1) demonstrated removal "at the initiative of the Secretary" under section 513(i)(2). Because the Steris Process Chemical Indicator was marketed as cleared, cleared only for use with the SS1, and removed from the market only upon FDA's demand and pursuant to a consent decree, it may no longer serve as a predicate device. Therefore, another predicate device should be identified. The Verify System 1 E Chemical Indicator is similar to other chemical indicators used with liquid chemical sterilants, such as the Serim® DISINTEK OPA

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Test Strips, which is a chemical indicator for use in determining whether the concentration of orthophthalaldehyde, the active ingredient in Cidex® OPA Solution, is above or below the minimum effective concentration (MEC) established for Cidex OPA Solution.

VI. Labeling

The firm provided the proposed labeling, which includes the intended use (indications for use) performance characteristics, instructions for use, storage conditions, expiration date, performance limitations, safety precautions, disposal instructions, and the name, address, and phone numbers of the manufacturer. The bottle label includes color blocks showing examples of the start, pass, and fail colors. The labeling uses the cleared name of the SS1E Processor. The labeling warns against use of the indicators by anyone with color blindness. The disposal instructions indicate that the product is **free** of lead and other heavy metals.

Comment: The firm should restate the disposal instructions to omit the reference to lead or other heavy metals or they should revise the statement to remove the word “free” and instead indicate that the product was not manufactured with lead or other heavy metals.

Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), the firm should include statements in the labeling warning the user to carefully assess the color change and follow the instructions closely.

VII. Sterilization/Shelf Life/Reuse

Sterilization: Indicators are provided non-sterile.

Reuse: The indicators are single use only.

Storage Conditions: Store at 43-86°F (6-30°C) and 30-60% relative humidity in original, tightly sealed bottle away from direct light. Do not store near heat, moisture, strong acids/alkalis, detergents, or oxidizing agents. The firm states in the labeling that the indicators can not be used as a permanent record.

Shelf life: The shelf life is 6 mos from the date opened or the printed expiration, whichever is shorter. Indicators expire the last day of the month printed on the label or 6 months after opening, whichever is first. The firm plans to claim a 24-month shelf life for the SS1E CI and provided a test protocol (App. A) for real time shelf life stability testing. However, testing to date, which the firm has provided in App. J, supports a 15-mo claim. The firm will limit their claim to 15 mos until testing to support a 24-mo claim has been successfully completed. The firm provided a promissory note in App. O indicating that they will not make shelf-life claims or stability claims without having the supporting testing information.

Open bottle: The firm provided the test results to date for open bottle testing in App. M per the protocol in App. A.

Comment: I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.

Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not

meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.

S1 Response: The firm provided the protocol for a new shelf life study and a promissory statement as requested. The firm also provide a 7-week interim report on a new opened bottle shelf life study and a promissory note as requested. See responses to 8/26/10 request below under Deficiencies.

VIII. Biocompatibility

The SS1E CIs do not have direct or indirect contact with patients. They do not contain lead or other heavy metals. However, the firm provided a Hazard Analysis/Risk Assessment in App. N.

IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

Comment:

➤ (b)(4)

(b)(4)

The indicator may become a lighter pink color when exposed to higher peracetic acid concentrations in S40 use dilution."

- In their current submission, the indications for use states, "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 darker pink when exposed to higher peracetic acid concentrations in S40 use dilution."
- In the performance testing in their previous submission, the firm showed ≥90% Pass at 1800 ppm PAA with beige color and 100% Fail at 1200 ppm PAA with gray/green or blue color. In response, FDA indicated that 1200 ppm PAA was too low of a fail condition to support the performance of the indicator.
- In their current submission, the firm indicates that the Pass/Fail criteria are now ≥90% Pass at 2200-2500 ppm PAA with a pink color and 100% Fail at 1750-1820 ppm with a beige color.

(b)(4)

In the current submission, the firm evaluated the three lots of the Verify SS1E CI as follows. The PAA concentration at the start of exposure was monitored for all studies in which the CI was processed in the SS1E. For PAA analysis, samples were collected through a sample port valve mounted in the

flow path of the processor at the start of exposure (10 sec) and near the end of the exposure (5 min 45 sec) to confirm that the cycle followed the expected PAA kinetics profile. The PAA concentration was 2253-2419 ppm for Pass testing conditions and 1772-1818 ppm for Fail testing conditions. Color blocks showing color samples were provided in Section 11 page 4.

Summary of Performance Testing

Study	Purpose	Results	Conclusion
1	Comparative Sensitivity: Verify CI can accurately distinguish between Pass and Fail – 2 runs each under Pass and Fail conditions using 15 CIs per lot for total of 90 CIs per test condition	100% Pass (b)(4) ppm PAA w/ Pink color 100% Fail (b)(4) ppm PAA w/ beige color	CI performed per the acceptance criteria.
2	Determine time interval required within which user must interpret the color change results after removal from processor	Up to 60 min, 100% still indicated Pass. Up to 30 min, 100% still indicated Fail.	The time interval required to interpret the result is 30 min.
3	Determine time required within which user must interpret the color change results after delay in opening the processor	Up to 60 min delay, 100% still indicated Pass. Up to 30 min delay, 100% still indicated Fail.	The time limit for removal from the processor is 30 min.
4	Verify that color change in indicator is specific to PAA when used in the SS1E processor	100% fail when exposed to Builders only	The indicator does not react in the absence of PAA.
5	Verify that processed indicator color is interpreted correctly by readers unaware of PAA concentration	3 readers correctly evaluated all indicators; the instructions were: Pass is pink or more pink than Pass reference color block; Fail is less pink than Pass reference color block	Firm concluded that color change can be correctly interpreted. However, the firm provided no color samples; it appears that the fail and pass colors are very close; it appears that the readers were from the lab and were already familiar with the color change
6	Evaluate effects that placing an endoscope in processor container may have on performance of strip	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Addition of a device to the chamber does not affect the performance of the CI strip.
7	Determine if exposure to UV radiation has effect on Start color of unprocessed strips	Color change noted in unprocessed strips exposed to UV No color change noted in unprocessed strips stored in closed bottle.	CI strips should be kept in the closed bottle.
8	Determine performance of CI over shelf life storage time and conditions: 5°C 22°C/80% RH 31°C/60% RH	Testing at 15 mos storage showed 100% Pass at (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	CI is stable through 15 mos storage under low and high temp, and low and high humidity; firm provided protocol and promissory note for ongoing testing

Study	Purpose	Results	Conclusion
9	Evaluate effects of aggressive chemicals on CI performance	Color change noted when CI strips in open bottle were stored near acidic and alkaline solutions.	CI strips should be kept in closed bottle.
10	Evaluate CI strip is affected by presence of contaminants , such as serum, saline and detergents.	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Contaminants do not affect the performance of the CI
11	Determine if performance of CI changes with time after bottle is opened	Firm indicates testing is ongoing. Results at 13 mos show failures. Firm limits opened bottle claim to 6 mos based on previous data.	Should limit claim to 3 mos until data available at 6 mos with current criteria; firm provided 7-wk interim data to support an opened bottle claim and promissory note to limit the claim to 3 mo until additional data are collected to support a longer claim.

Comments:

- It appears that the shelf life stability study is part of the ongoing shelf life stability testing that was also presented in the previous submission. However, for this interim report at 15 mos, the testing criteria were altered to meet the new Pass/Fail criteria. The shelf life stability testing is ongoing; the firm provided the protocol and a promissory note to complete the testing. Although, for the initial time points for the shelf stability study the CIs were evaluated per 90% Pass at 1800 ppm PAA and 100% Fail at 1200 ppm PAA, the data at 15 mos appear to demonstrate stability of the CI under the label storage conditions.
- The firm should provide a protocol for a new opened bottle study using the current color interpretation criteria and a promissory note that the claim will not be increased until testing supporting the claim has been completed.

S1 Response: The firm provided a protocol and promissory note as requested; see **Deficiencies for details.**

- The firm did not provide testing to demonstrate the stability of the color change over time. The color does not remain stable; therefore, the firm instructs the user to read the change within 30 min of cycle completion.

XII. Performance Testing – Animal – Not Applicable

XIII. Performance Testing – Clinical – Not Applicable

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XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

First Request – 8/25/10: In an email to Mr. Sullivan, I requested the following additional information:

- Please provide samples of the indicators showing the starting blue color, the fail gray/green and fail beige colors, and the pass pale pink color. It is unclear that the difference between beige and pale pink are easily distinguishable. For each indicator that is exposed to the System 1E process, please indicate the concentration of the peracetic acid that was measured during the

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exposure phase.

- Dr. Kapil Panguluri (INCB) and I discussed this issue in a 1:00 pm teleconference with the firm (Mr. Sullivan, Marcia Benedict and others). The firm referred me to pages 11-3 and 11-4 for color samples. The color blocks on page 11-4 are the reference blocks used during testing and that will appear on the device label. FDA indicated that the firm should provide additional blind testing with readers that are not associated with Steris Corp. Testing should be conducted with PAA concentrations of (b)(4) to help better determine a user's ability to correctly interpret the color change, particularly under worst case conditions at the MRC of 1800 ppm to determine if the user can distinguish correctly between beige and pale pink. The S40 Sterilant solution is generated by dilution in the SS1E and is single use. (b)(4). Therefore, it should only be in limited situations when the user would be faced with reading this color difference. Testing presented in the 510(k) for the SS1E showed that the system reliably and predictably generates solution at the nominal concentration. In addition, labeling statements will be added to ensure that the user carefully interprets the color of the processed indicator.
- In addition, I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.
- Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.
- In an email dated **8/26/10**, I provided the firm with a summary of our discussion and requested the following information. The firm provided their S1 response as shown below.
 - a. Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (b)(4) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.

S1 Response: The firm provided the report for a new study with 5 health care workers currently in device reprocessing as readers. The readers were not associated with Steris and were given instruction on reading the indicators. 15 CIs from each of 3 lots were processed in the SS1E (b)(4)

(b)(4)

(b)(4)

The results showed that all CIs processed (b)(4) were read as Pass (pink or more pink than the pass reference color block). Also, all CIs processed (b)(4) read as Fail (less

SZ

pink than the pass reference color block).

- b. Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol for a shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples will be stored under three different storage conditions and evaluated for physical characteristics and for color change following exposure in the SS1F to Pass conditions

(b)(4)

from each of three lots will be evaluated at each time point over 2 years. The protocol appears to be adequate. The firm provided a promissory statement certifying that the firm will not extend the shelf life claim beyond 15 mos until real time data supporting the claim have been collected.

- c. Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.

S1 Response: The firm provided the protocol 7 week interim report for an opened bottle shelf life stability study that incorporates the current color interpretations as part of the acceptance criteria. Samples were stored under three different storage conditions. The bottles were opened 3 times per week for 7 weeks. Unopened control bottles were stored similarly, but were only opened at the evaluation time point. The CIs were evaluated for color change following exposure in the SS1E to Pass conditions (b)(4) PAA) and to Fail conditions (b)(4) 3 strips per bottle from each of three lots were evaluated at 7 weeks. The results showed that all test strips performed per the acceptance criteria. The firm provided a promissory statement certifying that the firm will not extend the opened bottle shelf life claim beyond 3 mos until real time data supporting the claim have been collected.

Third request – 11/8/10: In an email to to Mr. Sullivan, I requested the following additional information:

1. The Steris System 1E was cleared as the "Steris System 1 E Liquid Chemical Sterilant Processing System" for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. Please ensure that all final documentation, including your Indications for Use Statement, 510(k) Summary, and labeling, reflect the FDA-cleared name, Steris System 1 E Liquid Chemical Sterilant Processing System.
2. In your labeling for the subject device, please restate the disposal instructions to omit the reference to lead or other heavy metals. Alternatively, please revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals. This recommendation is based on the fact that demonstrating that the indicators are "free" of lead or other heavy metals is not possible using current analytical methods.
3. Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), please add statements to the labeling warning the user to carefully assess the color change and to carefully follow the instructions.

4. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary located under Tab 5 of your submission, FDA believes that your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:
- a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
 - b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.
 - c. Please include a summary of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria (if applicable) and intended uses.
 - d. Please provide a conclusion statement that summarizes the data to demonstrate Substantial Equivalence.

Final Request:

***The firm will need to change the predicate in their 510(k) Summary.**

XVI. Contact History

08/25/10: Email request for information and Teleconference with firm
08/26/10: Email request to firm and document placed on hold

XVII. Recommendation: I recommend that the document, K102217, be placed ON PHONE HOLD pending receipt of the above additional information.

Regulation Number: 21 CFR 880.2800
Regulation Name: Physical/chemical sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ



Elaine Schalk Mayhall, Ph.D.



Elizabeth Claverie, M.S.

11-8-10

Date

11-8-10

Date

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COVER SHEET MEMORANDUM

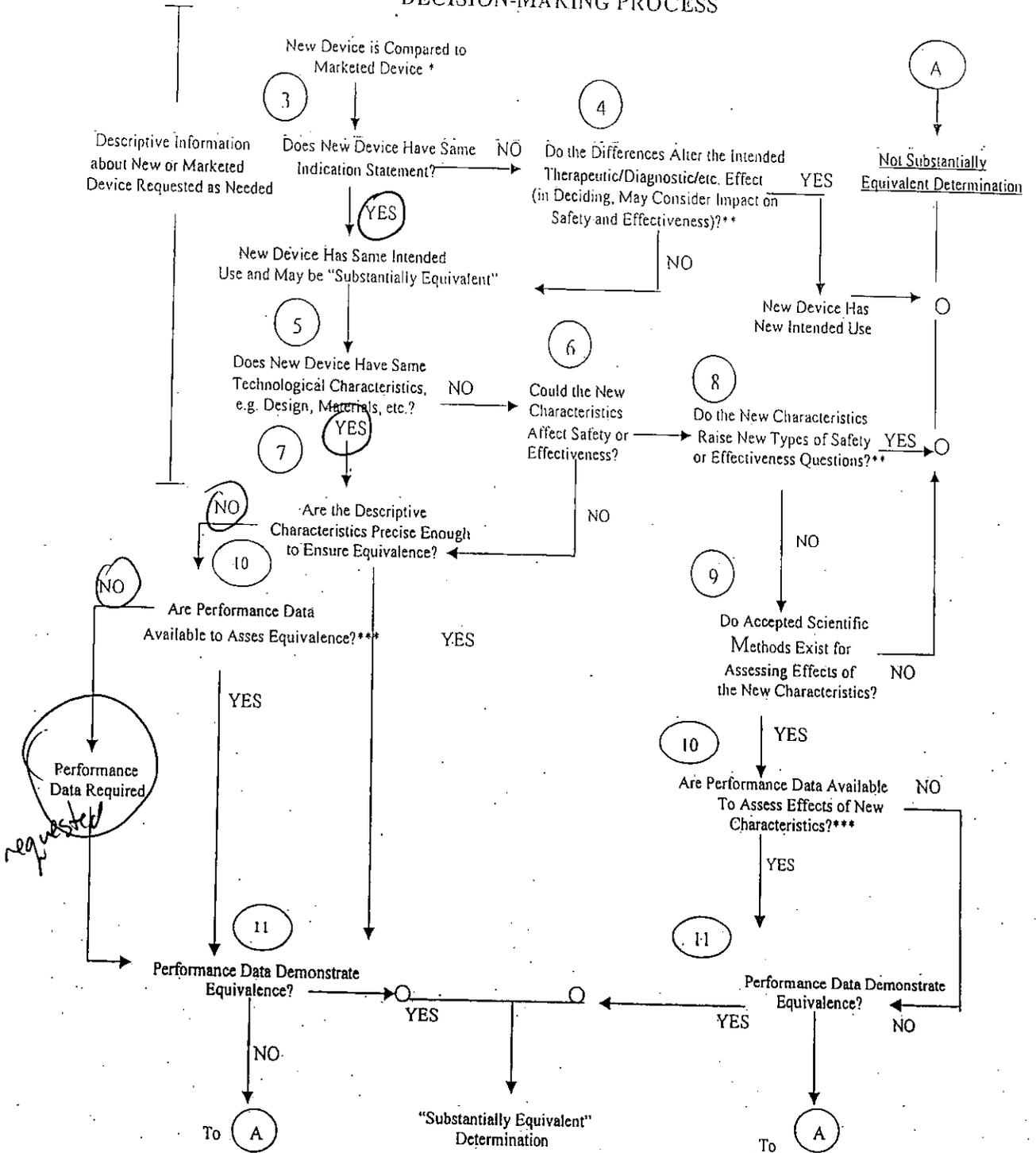
From: Reviewer Name Elaine Schalk Mayhall
 Subject: 510(k) Number K102217
 To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <=21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days -< 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years -< 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years -< 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
 - ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
 - ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.
- Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102217

Date: August 26, 2010
To: The Record
From: Elaine S. Mayhall, Ph.D.

Office: ODE
Division: INCB/DAGID

510(k) Holder: Steris Corp.
Device Name: Verify System 1E Chemical Indicator
Contact: Robert F. Sullivan
Phone: 440-392-7695
Fax: 440-357-9198
Email: Rsullivan@steris.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Verify System 1E Chemical Indicator into interstate commerce. The indicator is specifically for use in the Steris System 1E Liquid Chemical Sterilization System (NAME?), cleared under K090036. (b)(4)

(b)(4)

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

Table with 4 columns: Requirement, YES, NO, N/A. Rows include Required Elements for 510(k) Summary (21 CFR 807.92) with sub-rows for labeling, contact info, date, device name, predicate, description, and intended use.

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		YES	NO	N/A
Technological characteristics	if same, a summary of comparison of technological characters		X	
	If different, a summary of how do they compare to the Predicate		X	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 			
	Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)				
	Signed verbatim statement			

Comment: The firm should revise their Summary as indicated above. The firm will need to identify a new predicate because the SS1 CI cannot serve as a predicate.

III. Device Description

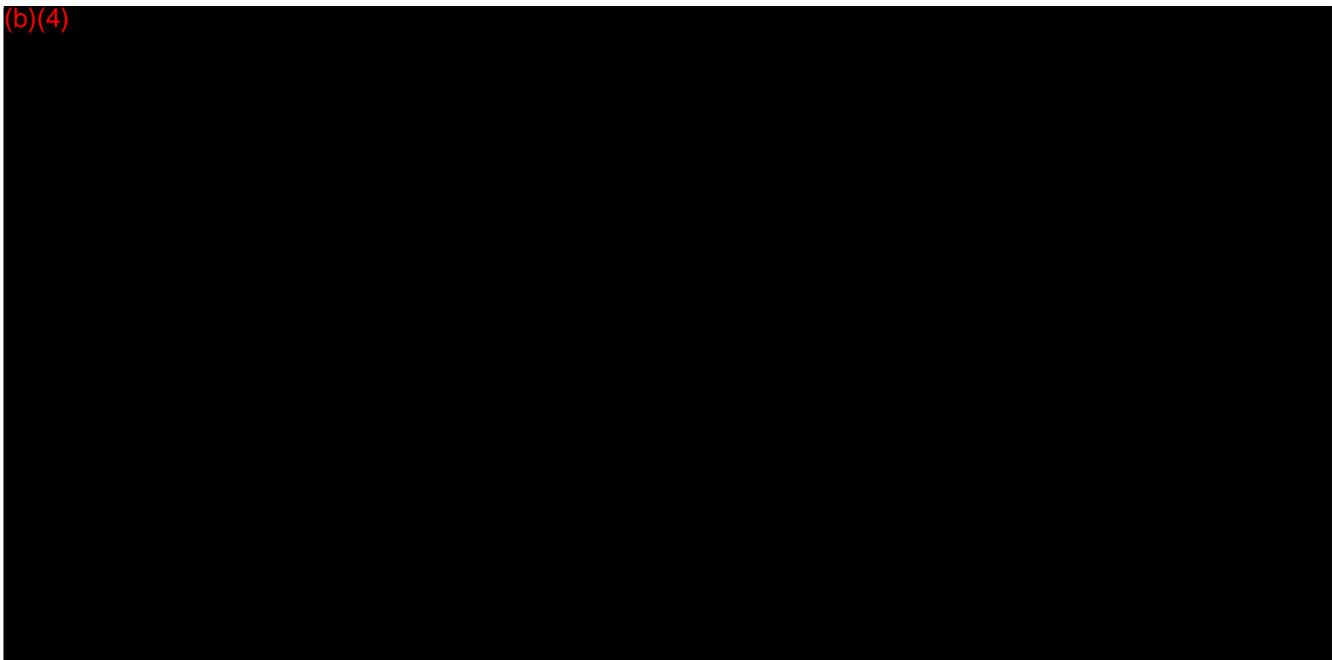
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Verify® System 1E Chemical Indicator (SS1E CI) is a single use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant permeable laminate made of polyether amide to protect the strip from damage during handling and prevent the indicator ink from leaching from the substrate. It 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 Sterilization System* processor during a processing cycle. The CI is placed in the system by clipping it to the dedicated peg in the processor tray. The instructions direct the user to read the color within 30 min of the cycle completion.

The ink is screen printed onto the substrate. The polyether amide laminated then is adhesively bonded to the polypropylene strip, covering the ink. The strip measures 10 mm x 83 mm. The firm indicates that the indicator spot undergoes a color change from blue to pink when exposed to a SS1E cycle using S40 Sterilant Concentrate at an in-use peracetic acid concentration of >1820 ppm (mg/L).

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(b)(4)



The CIs are packaged non-sterile in an airtight polypropylene bottle containing a maximum of 60 indicators with an integral desiccant sleeve to absorb moisture and a snap-top lid. Two bottles are packed in a shipper box along with a clip and the instructions for use.

Comment: The Steris System 1E was cleared as the Steris System 1 E Liquid Chemical Sterilant Processing System for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. The firm should use this name consistently throughout the document to refer to the cleared system.

IV. Indications for 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 a darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.

Comment: (b)(4)

(b)(4)

V. Predicate Device Comparison

The firm indicates that the predicate device for the Verify® System 1E Chemical Indicator is the Steris Verify Chemical Indicator for Steris System 1 Sterile Processing System, cleared as Verify SPI Chemical Indicator under K052535.

Comment: The consent decree (based on QSR violations) for the Steris System 1 Processor (SS1) demonstrated removal "at the initiative of the Secretary" under section 513(i)(2). Because the Steris Process Chemical Indicator was marketed as cleared, cleared only for use with the SS1, and removed from the market only upon FDA's demand and pursuant to a consent decree, it may no longer serve as a predicate device. Therefore, the firm must identify another predicate device and provide a comparison with the new predicate device.

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VI. Labeling

The firm provided the proposed labeling, which includes the intended use (indications for use) performance characteristics, instructions for use, storage conditions, expiration date, performance limitations, safety precautions, disposal instructions, and the name, address, and phone numbers of the manufacturer. The bottle label includes color blocks showing examples of the start, pass, and fail colors. The labeling uses the cleared name of the SS1E Processor. The labeling warns against use of the indicators by anyone with color blindness. The disposal instructions indicate that the product is **free** of lead and other heavy metals.

Comment: The firm should restate the disposal instructions to omit the reference to lead or other heavy metals or they should revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals.

Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), the firm should include statements in the labeling warning the user to carefully assess the color change and follow the instructions closely.

VII. Sterilization/Shelf Life/Reuse

Sterilization: Indicators are provided non-sterile.

Reuse: The indicators are single use only.

Storage Conditions: Store at 43-86°F (6-30°C) and 30-60% relative humidity in original, tightly sealed bottle away from direct light. Do not store near heat, moisture, strong acids/alkalis, detergents, or oxidizing agents. The firm states in the labeling that the indicators can not be used as a permanent record.

Shelf life: The shelf life is 6 mos from the date opened or the printed expiration, whichever is shorter. Indicators expire the last day of the month printed on the label or 6 months after opening, whichever is first. The firm plans to claim a 24-month shelf life for the SS1E CI and provided a test protocol (App. A) for real time shelf life stability testing. However, testing to date, which the firm has provided in App. J, supports a 15-mo claim. The firm will limit their claim to 15 mos until testing to support a 24-mo claim has been successfully completed. The firm provided a promissory note in App. O indicating that they will not make shelf-life claims or stability claims without having the supporting testing information.

Open bottle: The firm provided the test results to date for open bottle testing in App. M per the protocol in App. A.

Comment: I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.

Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit

the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.

VIII. Biocompatibility

The SS1E CIs do not have direct or indirect contact with patients. They do not contain lead or other heavy metals. However, the firm provided a Hazard Analysis/Risk Assessment in App. N.

IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

Comment:

➤ (b)(4)

(b)(4)

The indicator may become a lighter pink color when exposed to higher peracetic acid concentrations in S40 use dilution.”

➤ In their current submission, the indications for use states, “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 darker pink when exposed to higher peracetic acid concentrations in S40 use dilution.”

➤ In the performance testing in their previous submission, the firm showed ≥90% Pass at 1800 ppm PAA with beige color and 100% Fail at 1200 ppm PAA with gray/green or blue color. In response, FDA indicated that 1200 ppm PAA was too low of a fail condition to support the performance of the indicator.

➤ In their current submission, the firm indicates that the Pass/Fail criteria are now (b)(4)

(b)(4)

(b)(4)

In the current submission, the firm evaluated the three lots of the Verify SS1E CI as follows. The PAA concentration at the start of exposure was monitored for all studies in which the CI was processed in the SS1E. (b)(4)

(b)(4)

(b)(4)

Color

blocks showing color samples were provided in Section 11 page 4.

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Summary of Performance Testing

Study	Purpose	Results	Conclusion
1	Comparative Sensitivity: Verify CI can accurately distinguish between Pass and Fail – 2 runs each under Pass and Fail conditions using 15 CIs per lot for total of 90 CIs per test condition	100% Pass (b)(4) ppm PAA w/ Pink color 100% Fail (b)(4) ppm PAA w/ beige color	CI performed per the acceptance criteria.
2	Determine time interval required within which user must interpret the color change results after removal from processor	Up to 60 min, 100% still indicated Pass. Up to 30 min, 100% still indicated Fail.	The time interval required to interpret the result is 30 min.
3	Determine time required within which user must interpret the color change results after delay in opening the processor	Up to 60 min delay, 100% still indicated Pass. Up to 30 min delay, 100% still indicated Fail.	The time limit for removal from the processor is 30 min.
4	Verify that color change in indicator is specific to PAA when used in the SS1E processor	100% fail when exposed to Builders only	The indicator does not react in the absence of PAA.
5	Verify that processed indicator color is interpreted correctly by readers unaware of PAA concentration	3 readers correctly evaluated all indicators; the instructions were: Pass is pink or more pink than Pass reference color block; Fail is less pink than Pass reference color block	Firm concluded that color change can be correctly interpreted. However, the firm provided no color samples; it appears that the fail and pass colors are very close; it appears that the readers were from the lab and were already familiar with the color change
6	Evaluate effects that placing an endoscope in processor container may have on performance of strip	100% Pass (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	Addition of a device to the chamber does not affect the performance of the CI strip.
7	Determine if exposure to UV radiation has effect on Start color of unprocessed strips	Color change noted in unprocessed strips exposed to UV No color change noted in unprocessed strips stored in closed bottle.	CI strips should be kept in the closed bottle.
8	Determine performance of CI over shelf life storage time and conditions: 5°C 22°C/80% RH 31°C/60% RH	Testing at 15 mos storage showed 100% Pass at (b)(4) ppm PAA 100% Fail (b)(4) ppm PAA	CI is stable through 15 mos storage under low and high temp, and low and high humidity; firm provided protocol and promissory note for ongoing testing
9	Evaluate effects of aggressive chemicals on CI performance	Color change noted when CI strips in open bottle were stored near acidic and alkaline solutions.	CI-strips should be kept in closed bottle.
10	Evaluate CI strip is affected by presence of contaminants , such	100% Pass (b)(4) ppm PAA	Contaminants do not affect the performance

Study	Purpose	Results	Conclusion
	as serum, saline and detergents.	100% Fail (b)(4) ppm PAA	of the CI
11	Determine if performance of CI changes with time after bottle is opened	Firm indicates testing is ongoing. Results at 13 mos show failures. Firm limits opened bottle claim to 6 mos based on previous data.	Should limit claim to 3 mos until data available at 6 mos with current criteria

Comments:

- It appears that the shelf life stability study is part of the ongoing shelf life stability testing that was also presented in the previous submission. However, for this interim report at 15 mos, the testing criteria were altered to meet the new Pass/Fail criteria. The shelf life stability testing is ongoing; the firm provided the protocol and a promissory note to complete the testing. Although, for the initial time points for the shelf stability study the CIs were evaluated per 90% Pass at 1800 ppm PAA and 100% Fail at 1200 ppm PAA, the data at 15 mos appear to demonstrate stability of the CI under the label storage conditions.
- The firm should provide a protocol for a new opened bottle study using the current color interpretation criteria and a promissory note that the claim will not be increased until testing supporting the claim has been completed.
- The firm did not provide testing to demonstrate the stability of the color change over time. The color does not remain stable; therefore, the firm instructs the user to read the change within 30 min of cycle completion.

XII. Performance Testing – Animal – Not Applicable

XIII. Performance Testing – Clinical – Not Applicable

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWC

HART%20DECISION%20TREE%20DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

First Request – 8/25/10: In an email to Mr. Sullivan, I requested the following additional information:

- Please provide samples of the indicators showing the starting blue color, the fail gray/green and fail beige colors, and the pass pale pink color. It is unclear that the difference between beige and pale pink are easily distinguishable. For each indicator that is exposed to the System 1E process, please indicate the concentration of the peracetic acid that was measured during the exposure phase.
 - Dr. Kapil Panguluri (INCB) and I discussed this issue in a 1:00 pm teleconference with the firm (Mr. Sullivan, Marcia Benedict and others). He referred me to pages 11-3 and 11-4 for color samples. The color blocks on page 11-4 are the reference blocks used during testing and that will appear on the device label. FDA indicated that the firm should provide additional blind testing with readers that are not associated with Steris Corp. Testing should be conducted with PAA concentrations of (b)(4) help better determine a user's ability to correctly interpret the color change, particularly under worst case conditions at the MRC of 1800 ppm to determine if the user can distinguish correctly between beige and pale pink. The S40 Sterilant solution is generated by dilution in the SS1E and is single use. (b)(4) Therefore, it should only be in limited situations when the user would be faced with reading this color difference. Testing presented in the 510(k) for the SS1E showed that the system reliably and predictably generates solution at the nominal concentration. In addition, labeling statements will be added to ensure that the user carefully interprets the color of the processed indicator.
 - In addition, I requested that the firm initiate a new shelf life stability study and provide FDA with a new shelf life stability protocol using the current criteria for reading the indicator. FDA agreed that the shelf life data using the previous color interpretation criteria and the current 15 mo shelf life data using the current color interpretation and the previous data using the old interpretation is adequate to support a 15 mo shelf life for the indicator at this time. However, any extension of the shelf life must be supported by real time data with the current color interpretation acceptance criteria.

- Regarding the open bottle stability testing, the firm indicated that they now have 6 mo data available. I asked that they provide us with the data. In the current submission, the firm provided 13 mo data testing per the current color interpretation criteria. The results showed that the indicator does not meet the acceptance criteria 13 mos after the bottle is opened. The labeling limits the shelf life after opening the bottle to 6 mos or the printed shelf life expiration date. The firm should provide a protocol for a new open bottle shelf life study that uses the current color interpretations as part of the acceptance criteria. For now, the firm should limit the open bottle claim to 3 mos until 6 mos data supporting the claim can be generated. The firm should provide a promissory note regarding the testing and the claim.
- In an email dated 8/26/10, I provided the firm with a summary of our discussion and requested the following information.
 - a. Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (b)(4) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.
 - b. Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.
 - c. Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.

Third request: After the performance testing has been completed and found acceptable, the firm should address the following:

1. *The consent decree (based on QSR violations) for the Steris System 1 Processor (SS1) demonstrated removal "at the initiative of the Secretary" under section 513(i)(2). Because the Steris Process Chemical Indicator was marketed as cleared, cleared only for use with the SS1, and removed from the market only upon FDA's demand and pursuant to a consent decree, it may no longer serve as a predicate device. Therefore, the firm must identify another predicate device and provide a comparison with the new predicate device. **This can only be done after the firm has received a letter from CDRH indicating that the SS1 CI cannot serve as a predicate.***
2. The Steris System 1E was cleared as the Steris System 1 E Liquid Chemical Sterilant Processing System for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. The firm should use this name consistently throughout the document to refer to the cleared system.
3. The firm should restate the disposal instructions to omit the reference to lead or other heavy metals or they should revise the statement to remove the word "free" and instead indicate that the product was not manufactured with lead or other heavy metals.
4. Because it may be difficult to distinguish between the fail color (beige) and the pass color

(pale pink), the firm should include statements in the labeling warning the user to carefully assess the color change and follow the instructions closely.

5. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary located under Tab 5 of your submission, FDA believes that your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:
 - a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or
 - b. If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.
 - c. Please include a summary of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria (if applicable) and intended uses.
 - d. Please provide a conclusion statement that summarizes the data to demonstrate Substantial Equivalence.

XVI. Contact History

08/25/10: Email request for information and Teleconference with firm

08/26/10: Email request to firm and document placed on hold

XVII. Recommendation: I recommend that the document, K102217, be placed ON HOLD pending receipt of the above additional information.

Regulation Number: 21 CFR 880.2800

Regulation Name: Physical/chemical sterilization process indicator

Regulatory Class: Class II

Product Code: JOJ



 Elaine Schalk Mayhall, Ph.D.

8/26/10

 Date

 Elizabeth Claverie, M.S.

 Date

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Mayhall, Elaine

From: Mayhall, Elaine
Sent: Thursday, August 26, 2010 11:35 AM
To: Sullivan, Robert
Cc: Claverie, Elizabeth F; Runner, Susan
Subject: Follow-up to 8-25-10 telephone conversation

Dear Mr. Sullivan:

I am following up on our telephone conversation yesterday, August 15, 2010, when we discussed the ability of the user to distinguish between beige and pale pink with the Verify System 1E Chemical Indicator (SS1E CI) at about 1820 ppm peracetic acid. As discussed, please provide the following additional information:

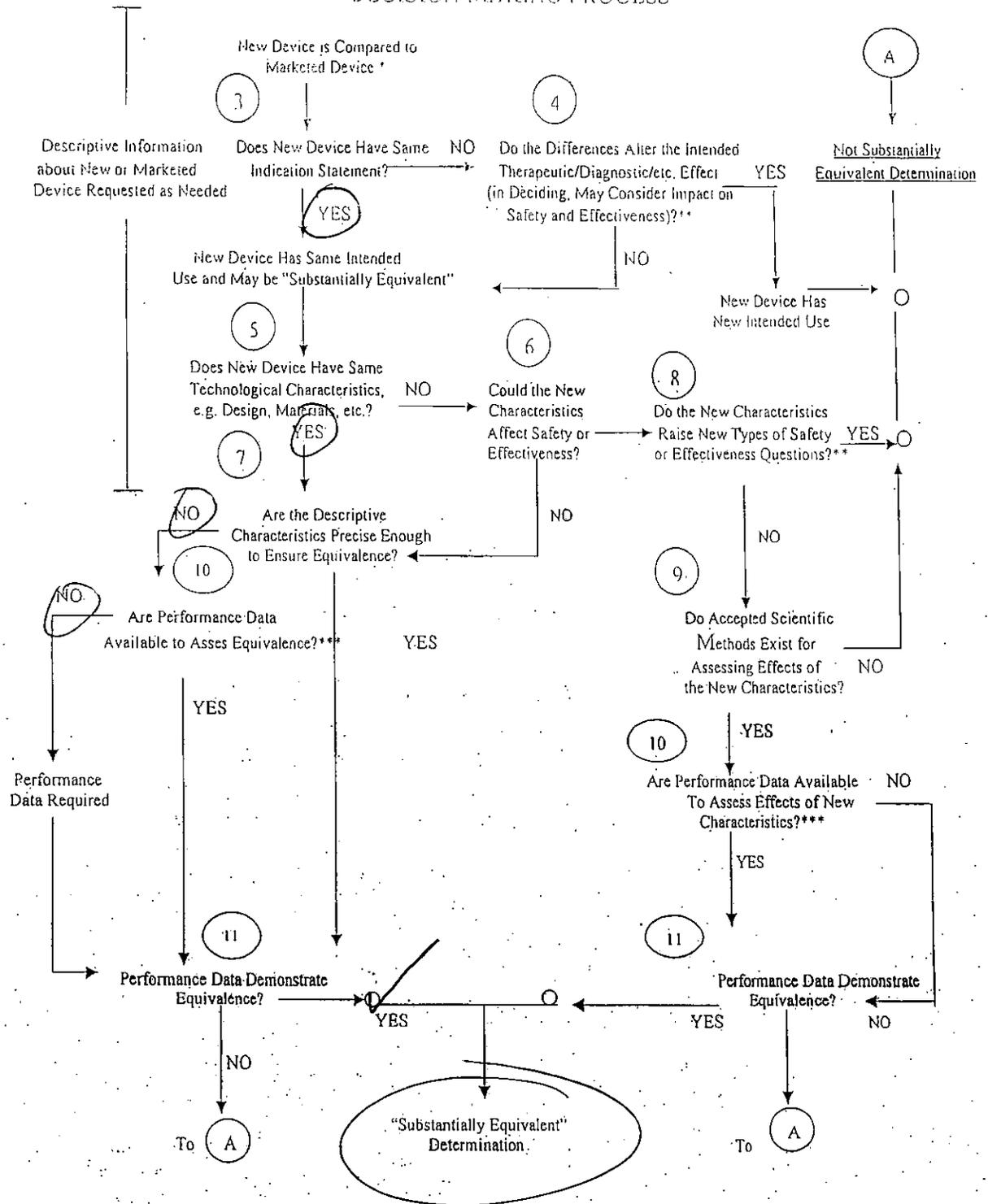
- a. Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (b)(4) peracetic acid) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.
- b. Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.
- c. In addition, after reviewing further the opened bottle shelf life stability data that you provided in your current submission, I note that the indicator failed testing at the 13 month time point using the current color interpretation criteria. The 6 month data are for the previous color interpretation criteria. Therefore, Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.

Please be advised that labeling revisions may be requested after all other issues have been resolved. We have placed your submission, K102217 for the Verify System 1E Chemical Indicator, on HOLD pending receipt of the above information. Please provide your response to the Document Mail Center within the next 30 days. If you have any questions, please contact me by phone at 301-796-6301 or by email.

Sincerely,

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
W066 Room 2612
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-6301
elaine.mayhall@fda.hhs.gov

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
 - ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
 - ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.
- Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

STERIS®



K102217/S1

FDA CDRH DMC

SEP 07 2010

Received

K-37

September 3, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Dr. Elaine Mayhall email dated August 26, 2010 concerning **K102217 Verify SYSTEM 1E Chemical Indicator** Request for Additional Information.

Dear Dr. Mayhall:

This is in response to your email of August 26, 2010, requesting additional information concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request, including an item-by-item response to your questions.

This document includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. We have made revisions as requested and they are reflected in the attached documentation

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert.Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,

Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

STERIS®



September 3, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Dr. Elaine Mayhall email dated August 26, 2010 concerning **K102217 Verify SYSTEM 1E Chemical Indicator** Request for Additional Information.

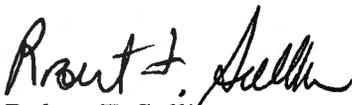
Dear Dr. Mayhall:

This is in response to your email of August 26, 2010, requesting additional information concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request, including an item-by-item response to your questions.

This document includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. We have made revisions as requested and they are reflected in the attached documentation

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert.Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,



Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

K102217 / S001
Response to 08/26/10 Request for Additional Information
For
Traditional 510(k) Premarket Notification
STERIS Corporation
Verify SYSTEM 1E Chemical Indicator

September 3, 2010

STERIS Corporation

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

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Appendices

- A 10029464: Laboratory Report for Study 5, Clinical Blind Reader Evaluation
- B Shelf Life Stability Protocol
- C Shelf Life Stability Promissory Note
- D 10029470 Laboratory Report for Study 11, Open Bottle Stability, 7 Week Interim Report
- E Opened Bottle Stability Promissory Note

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

1. *Please provide a new performance study for the Verify System 1E Chemical Indicator (SS1E CI) that evaluates the color change at about the minimum recommended concentration (1750-1820 ppm peracetic acid) of the sterilant using at least three readers that are not associated with Steris Corporation. We recommend that the readers be health care workers that currently are involved in reprocessing medical devices with liquid chemical sterilants.*

Response to Item 1:

The report for the new performance study for the Verify System 1E Chemical Indicator that evaluates the color changes at approximately the minimum recommended concentration (10029464: Laboratory Report for Study 5, Clinical Blind Reader Evaluation) is provided as **Appendix A** of this response. As recommended, the five readers utilized for this study were not associated with STERIS Corporation and consisted of health care workers currently involved in utilizing liquid chemical sterilants to reprocess medical devices. As detailed in the report, all acceptance criteria for this study were met.

2. *Please provide the protocol for a new shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. In addition, please provide a promissory note indicating that the shelf life of the indicator will not be increased until real time stability testing per the protocol has been completed.*

Response to Item 2:

It is the intention of STERIS Corporation to claim a 24 month shelf life for the Verify System 1E Chemical Indicator based on real time stability data. As requested, the protocol for a new shelf life stability to support this claim using the current color interpretations as part of the acceptance criteria is provided in **Appendix B** of this response. A promissory note indicating that the shelf life of the indicator will not be increased from the agreed-upon 15 months (based on data in the original submission) until real time stability testing per that new protocol has been completed is provided as **Appendix C** of this response.

At each of the time points and storage conditions specified in the protocol, the Verify SYSTEM 1E Chemical Indicators will be analyzed following processing in the SYSTEM 1E Liquid Chemical Sterilant Processing System as described in the Master Protocol

(b)(4)

(b)(4)

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

- At the completion of the processor cycle the processed CI strips will be removed and evaluated within 30 minutes of cycle completion. A standardized color reference panel will be used evaluate the color conversion of the CI strips.
 - The following instruction will be given to the examiner of the strips to determine if the processed strip is classified as PASS or FAIL:
 - A processed CI strip that is darker or less pink than the PASS reference square is a **FAIL**.
 - A processed CI strip that is equal to or more pink than the PASS reference color square is a **PASS**.
3. *In addition, after reviewing further the opened bottle shelf life stability data that you provided in your current submission, I note that the indicator failed testing at the 13 month time point using the current color interpretation criteria. The 6 month data are for the previous color interpretation criteria. Therefore, Please provide the protocol for a new opened bottle shelf life stability study that uses the current color interpretations as part of the acceptance criteria to support stability of the indicator. Based on the fail results at 13 months and the lack of data using the current color interpretation criteria, we recommend that you limit the opened bottle shelf life claim at this time to 3 months. In addition, please provide a promissory note indicating that the opened bottle shelf life claim of the indicator will not be increased until real time stability testing per the protocol has been completed.*

Response to Item 3:

It is the intention of STERIS Corporation to claim a 6 month opened bottle stability for the Verify System 1E Chemical Indicator. The protocol to be utilized for this study has been provided in the original submission (K102217, Protocol 10028753: Verification of the Chemical Indicator for use in the STERIS SYSTEM 1E Liquid Chemical Sterilant Processor, Section 5.11). This protocol uses the current color interpretations as part of the acceptance criteria and has been followed in generating the initial and 7-week open bottle stability data. Per FDA's verbal request in a phone conference on August 25th, the interim report for the opened bottle stability study with data for the initial and 7-week time points is provided as **Appendix D** which demonstrates that all acceptance criteria were met at this time point.

Also, regarding the previously submitted 13 month opened bottle stability data, we agree that the proposed indicator did fail the study with respect to the acceptance criteria given in the associated protocol. However, we would respectfully like to point out the indicator only failed by indicating failure well above MRC of peracetic acid; i.e. the articles failed safe and should not affect the safety or effectiveness of the Verify SYSTEM 1E Chemical Indicator.

Regardless, as suggested by FDA, the opened bottle shelf life claim will be limited to 3 months at this time and a promissory note indicating that the opened bottle shelf life claim of the Verify SYSTEM 1E CI will not be increased until real time stability testing through any longer time claimed has been completed is provided as **Appendix E**.

APPENDIX A

10029464 Laboratory Report for Study 5, Clinical Blind Reader Evaluation

Released

CONFIDENTIAL
STERIS CORPORATION

Laboratory Report for Study 5, Clinical Blind Reader Evaluation

10029464

In Support of K102217 / S001
Response to 08/26/10 Request for Additional Information
For
Traditional 510(k) Premarket Notification
STERIS Corporation
Verify SYSTEM 1E Chemical Indicator

APPENDIX B

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**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

APPENDIX C

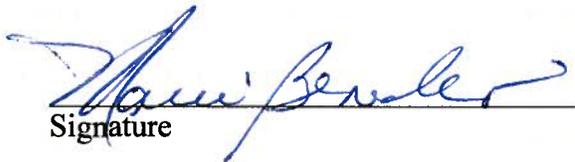
**Shelf Life Stability Promissory Note
For
Verify SYSTEM 1E CI**

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**



**Shelf Life Stability Certification Statement
For the proposed
Verify SYSTEM 1E Chemical Indicator**

I certify that, in my capacity as Director, Regulatory Affairs of STERIS Corporation, claims for shelf life stability for the proposed Verify SYSTEM 1E Chemical Indicator will not be extended beyond 15 months until real time stability testing has been completed per protocol and satisfactory testing information obtained.


Signature

9/3/10
Date

Marcia Benedict
Director, Regulatory Affairs

APPENDIX D

10029470 Laboratory Report for Study 11, Open Bottle Stability, 7 Week Interim Report

Released

CONFIDENTIAL
STERIS CORPORATION

Laboratory Report for Study 11, Open Bottle Stability

7 Week Interim Report

10029470

In Support of K102217 / S001
Response to 08/26/10 Request for Additional Information
For
Traditional 510(k) Premarket Notification
STERIS Corporation
Verify SYSTEM 1E Chemical Indicator

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

APPENDIX E

**Opened Bottle Stability Promissory Note
For
Verify SYSTEM 1E CI**

**K102217/S001 STERIS Response to 08/26/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**



**Opened Bottle Stability Certification Statement
For the proposed
Verify SYSTEM 1E Chemical Indicator**

I certify that, in my capacity as Director, Regulatory Affairs of STERIS Corporation, the opened bottle shelf life claim of the Verify SYSTEM 1E Chemical Indicator will not be increased to beyond 3 months until real time stability testing has been completed per protocol and satisfactory testing information obtained.


Signature


Date

Marcia Benedict
Senior, Regulatory Affairs

K102217/52

STERIS®



November 10, 2010

FDA CDRH DMC

NOV 12 2010

Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Dr. Elaine Mayhall email dated November 8, 2010 Request for Additional Information concerning **K102217 Verify SYSTEM 1E Chemical Indicator**

Dear Dr. Mayhall:

This is in response to your email of November 8, 2010, requesting additional information concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request.

This document includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. We have made revisions as requested and they are reflected in the attached documentation.

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert_Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,

For R. Sullivan

Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

K-39



November 10, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Dr. Elaine Mayhall email dated November 8, 2010 Request for Additional Information concerning **K102217 Verify SYSTEM 1E Chemical Indicator**

Dear Dr. Mayhall:

This is in response to your email of November 8, 2010, requesting additional information concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request.

This document includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. We have made revisions as requested and they are reflected in the attached documentation.

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert.Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William.Brodbeck@steris.com.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robert F. Sullivan".

For R. Sullivan

Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

K102217 / S002
Response to 11/08/10 Request for Additional Information
For
Traditional 510(k) Premarket Notification
STERIS Corporation
Verify SYSTEM 1E Chemical Indicator

November 10, 2010

STERIS Corporation

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Appendices

- A Revised Instructions for Use
- B Revised 510(k) Summary

STERIS Responses to FDA numbered requests

- 1. The Steris System 1E was cleared as the “Steris System 1 E Liquid Chemical Sterilant Processing System” for liquid chemical sterilization of critical and semi-critical heat sensitive medical devices. Please ensure that all final documentation, including your Indications for Use Statement, 510(k) Summary, and labeling, reflect the FDA-cleared name, Steris System 1 E Liquid Chemical Sterilant Processing System.*

In your labeling for the subject device, please restate the disposal instructions to omit the reference to lead or other heavy metals. Alternatively, please revise the statement to remove the word “free” and instead indicate that the product was not manufactured with lead or other heavy metals. This recommendation is based on the fact that demonstrating that the indicators are “free” of lead or other heavy metals is not possible using current analytical methods.

Because it may be difficult to distinguish between the fail color (beige) and the pass color (pale pink), please add statements to the labeling warning the user to carefully assess the color change and to carefully follow the instructions.

Response to Item 1:

STERIS would like to respectfully note that the SYSTEM 1E was cleared as the “SYSTEM 1E Liquid Chemical Sterilant Processing System”. As requested, we have reviewed the proposed SYSTEM 1E CI’s Indications for Use Statement, 510(k) Summary, and labeling to ensure that all reflect the FDA-cleared name of the system.

Please refer to **Appendix A** for revised draft Instructions for Use that comply with FDA’s request to indicate that the device was manufactured without lead or heavy metals.

In addition, this version adds a bolded statement in the section titled Instructions for Use emphasizing the need for careful assessment of the color change, consistent with the existing instructions. The final bullet of the Performance Limitations section provides emphasis on following these instructions, along with instruction to obtain assistance from STERIS if needed.

FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary located under Tab 5 of your submission, FDA believes that your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary.

**K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

- a. *If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or*

If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.

Please include a summary of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria (if applicable) and intended uses.

Please provide a conclusion statement that summarizes the data to demonstrate Substantial Equivalence.

Response to item a:

Please refer to **Appendix B** for a revised 510(k) Summary that provides the requested information.

APPENDIX A

Proposed Instructions for Use For Verify[®] SYSTEM 1E Chemical Indicator

Verify[®] SYSTEM 1E Chemical Indicator

Verify[®] Chemical Indicator for SYSTEM 1E[™] Processor

For routine monitoring of SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate

Intended Use

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.

Performance Characteristics

The Chemical Indicator strips for the SYSTEM 1E Processor are used during each processing cycle to detect the presence of the active ingredient, peracetic acid, in the use dilution of S40 Sterilant Concentrate. The unprocessed chemical indicator is blue. When exposed to an effective concentration of peracetic acid found in the sterilant use dilution, the indicator changes color from blue through grey/beige to pink (see the reference colors on the bottle). The indicator's PASS color may become more pink when exposed to higher peracetic acid concentrations in the use dilution of S40 Sterilant Concentrate.

Test data demonstrates that the Verify Chemical Indicator for SYSTEM 1E Processor strips achieve a PASS result when exposed to peracetic acid concentrations greater than the MRC, 1820 mg/L, in use dilution of S40 Sterilant Concentrate within the SYSTEM 1E Processor.

Instructions for Use

1. Check the expiration date on the bottle. Do not use an indicator beyond the expiration date. If a new bottle is being opened, record the date it was first opened and the new 6 month expiration date on the bottle (see Expiration Date).
2. Remove an indicator strip from the bottle and re-close the bottle tightly. Compare the unexposed indicator with the START reference color block on the bottle. Do not use an indicator if the color of the indicator does not match the START reference color.

**K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

3. Using the clip provided, place one strip in a SYSTEM 1E Processor.
4. Start the processing cycle according to the operator manual for the SYSTEM 1E Liquid Chemical Sterilant Processing System.
5. Within 30 minutes of cycle completion, carefully retrieve the indicator strip and compare the indicator color with the reference color blocks on the bottle.
 - a. If the indicator color is the same as, or more pink than the PASS reference on the bottle label, the processed items may be used.

Carefully assess the color change immediately or within 30 minutes of cycle completion. To be evaluated as a PASS, the processed indicator strip must reach a color the same as, or more pink than, the PASS reference color on the bottle label.

- b. If the indicator does NOT meet the criteria defined above (5a), the items must not be used. Follow departmental procedures for reporting failures.

Storage Conditions

Store all unused indicator strips at 43-86°F (6-30°C) and 30-60% relative humidity (RH) in their original, tightly sealed bottles, away from direct light.

Do not store near heat, moisture, strong acids/alkalis, detergents or oxidizing agents.

Exposed indicators can not be maintained as a permanent record.

Expiration Date

The expiration date is stated on the bottle. After first opening the bottle, the shelf life is 6 months from the date opened, or the printed expiration, whichever is shortest. Do not use after the expiration date.

Indicators expire on the last day of the month printed on the label or 6 months after opening, whichever is first.

Performance Limitations

- This product is for single use only. Do not reuse partially processed indicators.
- Verify Chemical Indicators for SYSTEM 1E Processor strips are part of a quality control system for sterility assurance. They cannot be used as a sole means for validating the liquid chemical sterilization process.
- Verify Chemical Indicators for SYSTEM 1E Processor strips should not be used by anyone with color blindness specific to the colors in the indicators. Ensure that all users are able to distinguish processed and unprocessed indicator colors.
- All personnel involved must be trained in the proper use of the indicators and a system for reporting failures must be established.

**K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

- Please follow the instructions for use carefully. If there are any problems interpreting the results from the product, contact STERIS.

Safety Precautions

- This device contains encapsulated dyes, and is safe under normal conditions of use.
- This device is not intended for human consumption.

Disposal Instructions

This product was manufactured without lead and other heavy metals and may be disposed of as regular waste.

Manufactured in the UK
STERIS Corporation
5960 Heisley Road ■ Mentor, OH 44060 USA
440-354-2600 ■ 800- 548-4873

APPENDIX B

Revised 510(k) Summary

(Original Section 005)



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

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Robert F. Sullivan
Senior Director,
FDA Regulatory Affairs
Telephone: (440) 392-7695
Fax No: (440) 357-9198

Submission Date: November 10, 2010

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600



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 Device

Verify[®] Chemical Indicator for SYSTEM 1[®] Sterile Processing System (K052535), cleared as Verify SPI Chemical Indicator

3. Device Description

The Verify[®] SYSTEM 1E Chemical Indicator is a single-use chemical indicator consisting of a polypropylene 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 at the point of use in a SYSTEM 1E Liquid Chemical Sterilant Processing System during a processor 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.

**K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices consist of a printed indicator spot on an inert polymeric substrate, where the indicator spot is subsequently encapsulated by lamination with a transparent semi-permeable laminate. The active ingredients of the ink used for the proposed and predicate devices are similar chemical homologues.

Whereas the proposed device indicates a color change from blue to pink when exposed to concentrations of peracetic acid greater than (or equal to) 1820 ppm, the predicate device indicates a color change from purple to white when exposed to peracetic acid concentrations greater than (or equal to) 1800 ppm. However, the mechanism of action for inducing a color change (bleaching of a dye as a result of oxidation by peracetic acid) is identical for the proposed Verify[®] SYSTEM 1E Chemical Indicator and the predicate Verify[®] SPI Chemical Indicator.

Therefore, differences between the proposed and predicate peracetic acid concentration monitors are limited to minor differences in the indicator ink composition and minimum peracetic acid concentrations required to induce a color change. 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.

K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator

Testing	Results
Comparative Sensitivity and Specificity	<p align="center">PASS</p> <p>The Verify SYSTEM 1E Chemical Indicators can correctly identify PASS or FAIL conditions for PAA concentrations in the SYSTEM 1E Liquid Chemical Sterilant Processing System.</p>
Color Read Time	<p align="center">PASS</p> <p>The observed color on 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.</p>
Analytic Specificity	<p align="center">PASS</p> <p>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.</p>
Blind Reader	<p align="center">PASS</p> <p>Blind Readers correctly evaluated 179 of 179 randomly displayed processed Verify SYSTEM 1E Chemical Indicators exposed to processor cycles above and slightly below the minimum required concentration of PAA.</p>
Simulated Use Testing	<p align="center">PASS</p> <p>The addition of a medical device to the processing chamber does not affect the performance of the Verify SYSTEM 1E Chemical Indicator.</p>
UV Study	<p align="center">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicators protects the unprocessed strips from the effects of UV light.</p>
Shelf Life	<p align="center">PASS</p> <p>The Verify SYSTEM 1E Chemical Indicator maintains appropriate indicator characteristics after 15 months of storage.</p>
Effects of Aggressive Chemicals	<p align="center">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicator protects the unprocessed strips from the effects of aggressive chemicals.</p>
Effects of Contaminants	<p align="center">PASS</p> <p>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.</p>
Open Bottle Stability	<p align="center">PASS</p> <p>At the 13 month time point, the Verify SYSTEM 1E Chemical Indicators demonstrated the appropriate PASS or FAIL results based on the PAA concentration of the use dilution.</p>

**K102217/S002 STERIS Response to 11/08/10 Request for Additional Information
Verify SYSTEM 1E Chemical Indicator**

7. Conclusion

The performance testing has demonstrated that the Verify SYSTEM 1E Chemical Indicator is substantially equivalent to its predicate in its ability to determine when an efficacious dose of peracetic acid has been delivered during the SYSTEM 1E Processor cycle and raises no new questions of safety or effectiveness.

K102217/S3



FDA CDRH DMC

November 17, 2010

NOV 18 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Received

NOV 18 2010

K17

RE: Dr. Elaine Mayhall email dated November 15, 2010 Request for Clarification concerning **K102217 Verify SYSTEM 1E Chemical Indicator**

Dear Dr. Mayhall:

This is in response to your email of November 15, 2010, requesting clarification concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request.

This document includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. We have made revisions as requested and they are reflected in the attached documentation.

If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert_Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,

For R.Sullivan

Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation



November 17, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Dr. Elaine Mayhall email dated November 15, 2010 Request for Clarification concerning **K102217 Verify SYSTEM 1E Chemical Indicator**

Dear Dr. Mayhall:

This is in response to your email of November 15, 2010, requesting clarification concerning the STERIS Corporation's Verify SYSTEM 1E Chemical Indicator, the subject of **K102217**. Enclosed are two copies, one hardcopy and one electronic copy that is an exact duplicate of the paper copy, of the response to your request.

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If you have any questions regarding this notification or require additional information, please contact me by telephone at 440-392-7695, by facsimile at 440-357-9198, or by email at Robert_Sullivan@steris.com. If I am unavailable you may contact Bill Brodbeck by telephone at 440-392-7690, by facsimile at 440-357-9198, or by email at William_Brodbeck@steris.com.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robert F. Sullivan", written over a circular scribble.

For R.Sullivan

Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation

K102217 / RC
Response to 11/15/10 Request for Clarification
For
Traditional 510(k) Premarket Notification
STERIS Corporation
Verify SYSTEM 1E Chemical Indicator

November 17, 2010

STERIS Corporation

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- A Predicate Comparison Table
- B Revised 510(k) Summary

STERIS Responses to FDA numbered requests

We do not believe that the Steris System 1 Chemical Indicator is appropriate as a predicate at this time. However, we believe that another chemical indicator cleared for a liquid chemical sterilant would be an appropriate predicate. Therefore, please provide the following additional information:

- 1. Please identify a new predicate, such as the Resert XL Test Strip, and provide a new comparison of the Verify System 1E Chemical Indicator with the new predicate.*

Response to Item 1:

Please see **Appendix A** for a comparison of predicates table that includes the identified more suitable predicate, the Verify Chemical Monitor for Resert Solutions K081600 (Resert XL Test Strip). We have also identified as a suitable new predicate the Reliance PI Chemical Indicator, K063285, which is substantially equivalent to the Verify SYSTEM 1E CI with respect to its intended use in an automated processing system using peracetic acid as the active germicide.

While STERIS does not fully comprehend, and therefore may not concur with, FDA's determination that the STERIS SYSTEM 1 Chemical Indicator is not an appropriate predicate device, we appreciate the opportunity to substitute predicates that are viewed by FDA as more suitable at this time.

Please provide a new 510(k) Summary that reflects the new predicate. The revised 510(k) summary should reflect the new predicate name and:

- a. If the technological characteristics between your device and the predicate are the same, please include a summary comparing the technological characteristics between the subject device and your identified predicates or*

If there are different technological characteristics, please include a summary comparing the technological modifications made to your device as it relates to your predicate devices.

Response to Item a:

Please refer to **Appendix B** for a revised 510(k) Summary that reflects the new predicates and compares these devices' technological characteristics.

APPENDIX A

Predicate Comparison Table For Verify SYSTEM 1E Chemical Indicator

**K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator**

Feature	Proposed Verify® SYSTEM 1E Chemical Indicator	Verify® Chemical Monitoring Strip for Resert Solutions (K081600)	Reliance CI Process Indicator (K063285)
Intended use	Process Indicator for peracetic acid in SYSTEM 1E Liquid Chemical Sterilant Processing System employing single use S40 Sterilant Concentrate	For use in confirming the minimum recommended concentration (MRC) of hydrogen peroxide, the active ingredient in Resert® XL HLD High-Level Disinfectant solution	Process Indicator for peracetic acid in Reliance Endoscope Processing System employing single use Reliance DG Dry Germicide
Device design - components	Indicator ink is printed onto polypropylene overlaid with a clear, permeable laminate	A paper pad impregnated with the indicator ink is attached to one end of a polymer film handle	Indicator ink is printed onto polypropylene overlaid with a clear, permeable laminate
Indicator agent	(b) (4)		
Mechanism of action			
Concentration required for the endpoint color change (PASS)	> 1820 ppm PAA	> 1.8% hydrogen peroxide	> 9000 mg/L PAA min dose [equivalent to >1500 mg/L PAA concentration for 6 minute exposure phase]
Disposable	Yes	Yes	Yes
Shelf-life	2 years (proposed)	6 months	1 year

APPENDIX B

Revised 510(k) Summary

(Original Section 005)



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

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Robert F. Sullivan
Senior Director,
FDA Regulatory Affairs
Telephone: (440) 392-7695
Fax No: (440) 357-9198

Submission Date: November 17, 2010

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

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.

**K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator**

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.

K102217/S002 STERIS Response to 11/15/10 Request for Clarification
Verify SYSTEM 1E Chemical Indicator

Testing	Results
Comparative Sensitivity and Specificity	<p style="text-align: center;">PASS</p> <p>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.</p>
Color Read Time	<p style="text-align: center;">PASS</p> <p>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.</p>
Analytic Specificity	<p style="text-align: center;">PASS</p> <p>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.</p>
Blind Reader	<p style="text-align: center;">PASS</p> <p>Blind Readers correctly evaluated 179 of 179 randomly displayed processed Verify SYSTEM 1E Chemical Indicators.</p>
Simulated Use Testing	<p style="text-align: center;">PASS</p> <p>The addition of a medical device to the processing chamber does not affect the performance of the Verify SYSTEM 1E Chemical Indicator.</p>
UV Study	<p style="text-align: center;">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicators protects the unprocessed strips from the effects of UV light.</p>
Shelf Life	<p style="text-align: center;">PASS</p> <p>The Verify SYSTEM 1E Chemical Indicator maintains appropriate indicator characteristics after 15 months of storage.</p>
Effects of Aggressive Chemicals	<p style="text-align: center;">PASS</p> <p>The bottle used to ship and store the Verify SYSTEM 1E Chemical Indicator protects the unprocessed strips from the effects of aggressive chemicals.</p>
Effects of Contaminants	<p style="text-align: center;">PASS</p> <p>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.</p>
Open Bottle Stability	<p style="text-align: center;">PASS</p> <p>At the 13 month time point, The Verify SYSTEM 1E Chemical Indicators demonstrated the appropriate FAIL results.</p>