



**FDA U.S. FOOD & DRUG**  
ADMINISTRATION

May 18, 2018

STERIS Corporation  
Marcia Benedict  
Senior Director, Regulatory Affairs  
5976 Heisley Rd  
Mentor, Ohio 44060

Re: K173428

Trade/Device Name: VERIFY Chemical Indicator for S40 Sterilant  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: Class II  
Product Code: JOJ  
Dated: January 31, 2018  
Received: February, 2018

Dear Marcia Benedict:

This letter corrects our substantially equivalent letter of March 2, 2018.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Tina Kiang  
-S

Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173428

Device Name

VERIFY® Chemical Indicator for S40® Sterilant

### Indications for Use (Describe)

The VERIFY Chemical Indicator for S40 Sterilant is a peracetic acid concentration indicator for routine monitoring of automated STERIS liquid chemical sterilant processing systems that employ S40 Sterilant Concentrate in a controlled cycle.

The unprocessed VERIFY Chemical Indicator for S40 Sterilant is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, 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 sterilant use dilution.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**STERIS®**



**510(k) Summary  
For  
VERIFY® Chemical Indicator for S40 Sterilant**

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Contact: Marcia L. Benedict  
Senior Director, Regulatory Affairs  
Telephone: (440) 392-7063  
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Submission Date: February 6, 2018

Premarket Notification Number: K173428

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

**1. Device Name**

Trade Name: VERIFY® Chemical Indicator for S40 Sterilant  
Models: N/A  
Common Name: Chemical Indicator.  
Classification Name: Physical/chemical sterilization process indicator  
Classification 21 CFR 880.2800  
Product Code JOJ

**2. Predicate Device**

VERIFY® Chemical Indicator for SYSTEM 1E Processor (K102217)

**3. Device Description**

The VERIFY® Chemical Indicator for S40 Sterilant is a single-use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end.

The subject device is physically identical to the predicate device.

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 monitors the peracetic acid (PAA) concentration of the STERIS S40 Sterilant Concentrate at the point of use in an automated liquid chemical sterilant processing system that uses S40 Sterilant Concentrate and provides a controlled 6-minute exposure at 45.5 – 60°C during a processing cycle.

**4. Intended Use**

The VERIFY® Chemical Indicator for S40 Sterilant is a peracetic acid concentration indicator for routine monitoring of STERIS automated liquid chemical sterilant processing systems that employ S40 Sterilant Concentrate in a controlled cycle.

The unprocessed VERIFY Chemical Indicator for S40 Sterilant is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, 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 sterilant use dilution.

**5. Description of Technological Similarities and Differences**

The proposed device and its predicate are physically identical. The liquid chemical sterilant exposure conditions monitored are identical.

The proposed device, like the predicate, indicates exposure to a targeted effective concentration of peracetic acid by a color change from blue through intermediate beige and then pink endpoint color when exposed for 6 minutes to concentrations of peracetic acid greater than 1820 ppm at 45.5 – 60°C during the liquid chemical sterilant processing system's standard cycle.

The more descriptive intended use statement will enable use of the VERIFY Chemical Indicator for S40 Sterilant in STERIS automated liquid chemical sterilant processors that use S40 Sterilant Concentrate and provide the same specific described and validated liquid chemical sterilant exposure parameters in a controlled automated cycle.

**Table 1. Device Comparison Table**

| <b>Feature</b> | <b>K173428 - Proposed<br/>VERIFY® Chemical<br/>Indicator for S40 Sterilant</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>K102217 - Predicate<br/>VERIFY® Chemical<br/>Indicator for SYSTEM 1E<br/>Processor</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Comparison</b>                                                                                                                                                                                |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended use   | <p>The VERIFY Chemical Indicator for S40 Sterilant is a peracetic acid concentration indicator for routine monitoring of STERIS automated liquid chemical sterilant processing systems that employ S40 Sterilant Concentrate in a controlled cycle.</p> <p>The unprocessed VERIFY Chemical Indicator for S40 Sterilant is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of &gt;1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, 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 sterilant use dilution.</p> | <p>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.</p> <p>The unprocessed Verify SYSTEM 1E Chemical Indicator is blue. When exposed to a concentration of &gt;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.</p> | <p>The proposed descriptive wording focuses on the S40 sterilant and the liquid chemical sterilization cycle exposure parameters monitored rather than on a specific processing system name.</p> |

**K173428/S001 STERIS Response to 12/29/17 Request for Additional Information  
VERIFY Chemical Indicator for S40 Sterilant**

| <b>Feature</b>                                             | <b>K173428 - Proposed<br/>VERIFY® Chemical<br/>Indicator for S40 Sterilant</b>                                                                                                                                         | <b>K102217 - Predicate<br/>VERIFY® Chemical<br/>Indicator for SYSTEM 1E<br/>Processor</b>                                                                                                                              | <b>Comparison</b> |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Device design - components                                 | Printed indicator ink printed onto polypropylene overlaid with a clear, permeable laminate                                                                                                                             | Printed indicator ink printed onto polypropylene overlaid with a clear, permeable laminate                                                                                                                             | Identical         |
| Sterilization method and cycles                            | Used in a liquid chemical sterilant processing system employing S40 Sterilant Concentrate to form a use dilution concentration of $\geq 1820$ ppm (mg/L) peracetic acid and provide 6 minutes exposure at 45.5 – 60°C. | Used in a liquid chemical sterilant processing system employing S40 Sterilant Concentrate to form a use dilution concentration of $\geq 1820$ ppm (mg/L) peracetic acid and provide 6 minutes exposure at 45.5 – 60°C. | Identical         |
| Mechanism of action                                        | Ink ingredients change color as a result of oxidation, resulting in blue to beige/pink color change.                                                                                                                   | Ink ingredients change color as a result of oxidation, resulting in blue to beige/pink color change.                                                                                                                   | Identical         |
| Peracetic acid concentration for the endpoint color change | > 1820 mg/L PAA                                                                                                                                                                                                        | > 1820 mg/L PAA                                                                                                                                                                                                        | Identical         |
| Disposable                                                 | Yes                                                                                                                                                                                                                    | Yes                                                                                                                                                                                                                    | Identical         |
| Shelf-life                                                 | 15 months;<br>pending change to 2 years                                                                                                                                                                                | 15 months;<br>pending change to 2 years                                                                                                                                                                                | Identical         |
| Open bottle shelf life                                     | 6 months                                                                                                                                                                                                               | 6 months                                                                                                                                                                                                               | Identical         |

**6. Description of Safety and Substantial Equivalence**

The proposed device and its predicate are physically identical. The liquid chemical sterilant exposure conditions monitored by the strip are identical.

The proposed device, like the predicate, indicates exposure to a targeted effective concentration of peracetic acid by a color change from blue through intermediate beige and then pink endpoint color when exposed for 6 minutes to concentrations of peracetic acid greater than 1820 ppm at 45.5 – 60°C during the liquid chemical sterilant processing system's standard cycle.

**7. Performance Testing**

The following table summarizes the non-clinical performance testing of the identical predicate device that has demonstrated that the product is safe and

**K173428/S001 STERIS Response to 12/29/17 Request for Additional Information  
VERIFY Chemical Indicator for S40 Sterilant**

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effective. This submission revises the product's name and its indications for use description, changes that raise no new questions of safety or effectiveness.

| Testing                                 | Results |
|-----------------------------------------|---------|
| Comparative Sensitivity and Specificity | PASS    |
| Color Read Time                         | PASS    |
| Analytic Specificity                    | PASS    |
| Blind Reader                            | PASS    |
| Simulated Use Testing                   | PASS    |
| UV Study                                | PASS    |
| Shelf Life for 24 months                | PASS    |
| Effects of Aggressive Chemicals         | PASS    |
| Effects of Contaminants                 | PASS    |
| Open Bottle Stability for 6 months      | PASS    |

**8. Conclusion**

The VERIFY Chemical Indicator for S40 Sterilant has met the established performance criteria. Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K102217), Class II (CFR 880.2800), product code JOJ.