DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 9, 2018

STERIS Corporation
Ms. Jennifer Nalepka
Senior Regulatory Affairs Specialist
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K172748
Trade/Device Name: VERIFY® V24 Self-Contained Biological Indicator
VERIFY® V24 Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Biological Sterilization Process
Regulatory Class: Class II
Product Code: FRC
Dated: January 09, 2018
Received: January 10, 2018

Dear Ms. Jennifer Nalepka :

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172748

Device Name
VERIFY V24 Self-Contained Biological Indicator

Indications for Use *(Describe)*
The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles:

- Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers
- Standard Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer
- Express, Flex Scope and Standard Cycles of the STERRAD® 100 NX Sterilizer

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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 number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K172748

Device Name

VERIFY V24 Challenge Pack

Indications for Use *(Describe)*

The VERIFY V24 Challenge Pack is intended for qualification testing of the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.

The VERIFY V24 Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The VERIFY V24 Challenge Pack is not intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing the Sterilizers.

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.**

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# 510(k) Summary
# For
# VERIFY® V24 Self-Contained Biological Indicator


**Sponsor Facility**

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

**Manufacturing Facility**

STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax No: (440) 392-7896

Contact: Jennifer Nalepka
Senior Regulatory Affairs Specialist

Telephone: (440) 392-7458
Fax No: (440) 357-9198
e-mail: jennifer_nalepka@steris.com


Submission Date: January 9, 2018

Premarket Notification Number: K172748

## 1. Device Name

| | |
|---|---|
| Trade Name: | VERIFY® V24 Self-Contained Biological Indicator |
| Common/usual Name: | Biological Indicator (BI, SCBI) |
| Device Classification: | Class II |
| Classification Name: | Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC) |

## 2. Predicate Device

VERIFY® V24 Self-Contained Biological Indicator, K140499

## 3. Description of Device

The VERIFY V24 Self-Contained Biological Indicator (SCBI) is used by healthcare facilites to monitor the V-PRO® Low Temperature Sterilization Systems. It is designed to accompany medical devices placed in the sterilizer.

The user places the VERIFY V24 Self-Contained Biological Indicator into the V-PRO Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the VERIFY V24 Self-Contained Biological Indicator can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The VERIFY V24 Self-Contained Biological Indicator is activated by sealing the vial and rupturing the medium ampoule using the STERIS VERIFY SCBI HP activator. The activator automatically seals the VERIFY V24 Self-Contained Biological Indicator vial and releases the growth media.

The activated SCBI is incubated at 55-60°C for ≥ 24 hours. The VERIFY V24 Self-Contained Biological Indicator indicates a pass if the media remains orange and non-turbid. The VERIFY V24 Self-Contained Biological Indicator indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

## 4. Intended Use/ Indications for Use

The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles:

- Non Lumen, Flexible, Lumen and Fast Non Lumen of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers
- Standard Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer
- Express, Flex Scope and Standard Cycles of the STERRAD® 100 NX Sterilizer

## 5. Summary of Technical Characteristics

A comparison of technical characteristics versus the predicate is summarized in **Table 5-1.**

**Table 5-1.** VERIFY V24 Self-Contained Biological Indicator Physical Description and Technological Properties vs the Predicate Device

| Feature | VERIFY V24 Self-Contained Biological Indicator (Proposed, K172748) | VERIFY V24 Self-Contained Biological Indicator (Predicate, K140499) | Comparison |
|---|---|---|---|
| Intended Use | The VERIFY V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles:<br>• Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers<br>• Standard Cycle of the STERRAD 100S Sterilizer<br>• Standard and Advanced Cycles of the STERRAD NX Sterilizer<br>• Express, Flex Scope and Standard Cycles of the STERRAD 100 NX Sterilizer | The VERIFY V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles:<br>• Lumen, Non Lumen and Flexible Cycles of the V-PRO 1, 1 Plus, maX and 60 Sterilizers<br>• Standard Cycle of the STERRAD 100S Sterilizer<br>• Standard and Advanced Cycles of the STERRAD NX Sterilizer<br>• Express, Flex Scope and Standard Cycles of the STERRAD 100 NX Sterilizer. | The proposed and predicate devices are identical. The Fast Non Lumen Cycle is a new cycle in the V-PRO maX 2 Low Temperature Sterilizer, which has been submitted in a separate premarket notification. |
| Indicator organism | *Geobacillus stearothermophilus* | *Geobacillus stearothermophilus* | Same |
| Mechanism of action | Visual detection of growth based on media color change in the presence of | Visual detection of growth based on media color change in the presence of | Same. Resistance testing and simulated use testing demonstrate appropriate |

| Feature | VERIFY V24 Self-Contained Biological Indicator (Proposed, K172748) | VERIFY V24 Self-Contained Biological Indicator (Predicate, K140499) | Comparison |
|---|---|---|---|
| | surviving indicator organisms. | surviving indicator organisms. | monitoring of indicated sterilization cycles. |
| Accessories | VERIFY Incubator and VERIFY SCBI HP Activator (optional) | VERIFY Incubator and VERIFY SCBI HP Activator (optional) | Same |
| Viable spore population | 2.0 – 3.4 x $10^6$ spore/BI | 2.0 – 3.4 x $10^6$ spore/BI | Same. Both contain greater than $10^6$ spores/BI. |
| Resistance characteristics | Resistance @ 2.7 mg/L $H_2O_2$:<br>• D-value 4.0 – 8.0 sec<br>• Survival Time 4 - 30 sec<br>• Kill Time ≤ 16 min | Resistance @ 2.7 mg/L $H_2O_2$:<br>• D-value 4.0 – 8.0 sec<br>• Survival Time 4 - 30 sec<br>• Kill Time ≤ 16 min | Same. Simulated use testing verifies suitability for use in claimed cycles. |
| Culture Conditions | 55- 60°C, media included in the VERIFY V24 Self-Contained Biological Indicator, 24 hour incubation time. | 55- 60°C, media included in the VERIFY V24 Self-Contained Biological Indicator, 24 hour incubation time. | Same. RIT Testing and ISO 11138-1 media testing verifies performance |
| Primary Packaging | Direct inoculum on plastic vial, glass ampoule with recovery media. | Direct inoculum on plastic vial, glass ampule with recovery media. | Same |
| Process indicator | VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change. | VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change. | Same |
| Shelf-life | 9 months: An 18-month shelf life is established for the SCBI however the throughput process indicator (K140515) has a shelf life of 9 months so the maximum labeled shelf life for the SCBI is 9 months | 9 months: An 18-month shelf life is established for the SCBI however the throughput process indicator (K140515) has a shelf life of 9 months so the maximum labeled shelf life for the SCBI is 9 months | Same |

## 6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-2** below.

**Table 5-2.** Summary of Non-clinical Testing

| Test | Acceptance Criteria | Conclusion |
|---|---|---|
| ¼, ½ & ¾ Cycle Performance | The performance of the the VERIFY V24 Self-Contained Biological Indicator in ¼, ½ or ¾ cycles was evaluated. Partial positive results were obtained in the ¼ and ½ cycles and all negative results were obtained in the ¾ cycle evaluations. | PASS |
| Growth Inhibition | Uninoculated VERIFY V24 Self-Contained Biological Indicators were processed in a Fast Non Lumen Cycle | PASS |

| Test | Acceptance Criteria | Conclusion |
|---|---|---|
| | and inoculated with low numbers (<100 CFU) of *Geobacillus stearothermophilus*. All tested the VERIFY V24 Self-Contained Biological Indicators exhibited growth. | |
| Simulated Use | VERIFY V24 Self-Contained Biological Indicators were processed in the Fast Non Lumen Cycle under simulated use conditions with the following results:<br>• All processed SCBIs exhibit negative growth results<br>• All processed SCBI Label PIs exhibit a "pass" result<br>• All processed CIs exhibit a "pass" result | PASS |

**Table 5-3.** Summary of Testing Previously Submitted for VERIFY V24 Self-Contained Biological Indicator (K140499)

| Test | Acceptance Criteria | Conclusion |
|---|---|---|
| Reduced Incubation Time (RIT) Testing | RIT testing performed per the FDA guidance on BI submissions is done to obtain 30 – 80% survival of exposed BI with a ≥ 97% correspondence between the 24-hour results and the conventional incubation time of 7 days. | PASS |
| Viable spore population | The viable spore population found in the VERIFY V24 Self-Contained Biological indicator must fall between 2.0 – 3.4 x $10^6$ spore/SCBI | PASS |
| D-value | D-value testing was performed per the FDA guidance on BI submissions. For the VERIFY V24 Self-Contained Biological Indicator, the D-value must be 4-8 seconds. | PASS |
| Survival Time | Survial time testing was performed per the FDA guidance on BI submissions. For the VERIFY V24 Self-Contained Biological Indicator, the survival time must be 4-30 seconds. | PASS |
| Kill Time | Kill time testing was performed per the FDA guidance on BI submissions. For the VERIFY V24 Self-Contained Biological Indicator, the kill time must be ≤ 16 min. | PASS |
| Hold Time | The performance of VERIFY V24 Self-Contained Biological Indicators held for 72 hours after exposure to VHP was evaluated. | PASS |

## 7. Conclusion

Based on the intended use, technological characteristics and nonclinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device, VERIFY V24 Self-Contained Biological Indicator (cleared in K140499), Class II (21 CFR 880.2800) product code FRC.

# 510(k) Summary
# For
# VERIFY® V24 Challenge Pack

**Sponsor Facility**

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

**Manufacturing Facility**

STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax No: (440) 392-7896

Contact: Jennifer Nalepka
Senior Regulatory Affairs Specialist

Telephone: (440) 392-7458
Fax No: (440) 357-9198
e-mail: jennifer_nalepka@steris.com

Submission Date: January 8, 2018

Premarket Notification Number: K172748

## 8. Device Name

| | |
|---|---|
| Trade Name: | VERIFY® V24 Challenge Pack |
| Common/usual Name: | Biological Indicator (BI) Process Challenge Device |
| Device Classification: | Class II |
| Classification Name: | Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC) |

## 9. Predicate Device

VERIFY® V24 Challenge Pack, K140499

## 10. Description of Device

The VERIFY V24 Challenge Pack is used by healthcare facilities for qualification testing of the V-PRO Low Temperature Sterilization Systems following installation, relocations, malfunctions or major repairs. The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital defined challenge load is not included.

The user places the VERIFY V24 Challenge Pack into the V-PRO Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the VERIFY HPU Chemical Indicator (CI) and the VERIFY V24 Self-Contained Biological Indicator (SCBI) contained in the challenge pack are retrieved. The CI is assessed for a passing color change immediately and the SCBI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The SCBI is activated by sealing the vial and rupturing the medium ampoule using the STERIS VERIFY SCBI HP activator. The activator automatically seals the SCBI vial and releases the growth media.

The activated SCBI is incubated at 55-60°C for ≥ 24 hours. The SCBI indicates a pass if the media remains orange and non-turbid. The SCBI indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

## 11. Intended Use/ Indications for Use

The VERIFY V24 Challenge Pack is intended for qualification testing of the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.

The VERIFY V24 Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The VERIFY V24 Challenge Pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in Sterilizer qualification.

## 12. Summary of Technical Characteristics

A comparison of technical characteristics versus the predicate is summarized in **Table 5-1.**

**Table 5-1.** VERIFY V24 Challenge Pack Physical Description and Technological Properties vs the Predicate Device

| Feature | VERIFY V24 Challenge Pack (proposed K172748) | VERIFY V24 Challenge Pack Predicate (K140499) | Comparison |
|---|---|---|---|
| Intended Use | The VERIFY V24 Challenge Pack is used for qualification testing of the Non Lumen, Flexible, Lumen and Fast Non Lumen cycles of the V-PRO Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs in healthcare facilities.<br><br>The VERIFY V24 Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.<br><br>The VERIFY V24 Challenge Pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in Sterilizer qualification testing. | The VERIFY® V24 Challenge Pack is intended for qualification testing of the Lumen, Non Lumen and Flexible cycles of V-PRO® Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.<br><br>The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.<br><br>The challenge pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in Sterilizer qualification testing. | The proposed and predicate devices are identical. The Fast Non Lumen Cycle is a new cycle in the V-PRO maX 2 Low Temperature Sterilizer, which has been submitted in a separate premarket notification. |

| Feature | VERIFY V24 Challenge Pack (proposed K172748) | VERIFY V24 Challenge Pack Predicate (K140499) | Comparison |
|---|---|---|---|
| Biological Indicator | VERIFY V24 Self-Contained Biological Indicator (subject of this submission) | VERIFY V24 Self-Contained Biological Indicator | Same |
| Class 1 Chemical Indicator | The VERIFY HPU Chemical Indicator (subject of a separate Premarket Notification) is placed inside the pouch.<br><br>A throughput process indicator is also located on the VERIFY V24 SCBI label. | The VERIFY HPU Chemical Indicator is placed inside the pouch.<br><br>A throughput process indicator is also located on the VERIFY V24 SCBI label. | Same |
| Means to distinguish processed from unprocessed | Chemical indicator of proposed device visible through the pack. | Chemical indicator of proposed device visible through the pack. | Same |

## 13. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-2** below.

**Table 5-2.** Summary of Non-clinical Testing

| Test | Acceptance Criteria | Conclusion |
|---|---|---|
| Comparitive Dose Response to Biological Model | The VERIFY V24 Challenge Pack was compared to the worst case biological model in the Fast Non Lumen Cycle. The challenge pack shall demonstrate equal or greater resistance as compared to the worst case biological model. | PASS |
| Simulated Use | VERIFY V24 Challenge Pack were processed in the Fast Non Lumen Cycle under simulated use conditions with the following results:<br>• All processed SCBIs exhibit negative growth results<br>• All processed SCBI Label PIs exhibit a “pass” result<br>• All processed CIs exhibit a “pass” result | PASS |

## 14. Conclusion

Based on the intended use, technological characteristics and nonclinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device, VERIFY V24 Challenge Pack (cleared in K140499), Class II (21 CFR 880.2800), product code FRC.