February 28, 2018

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

Re: K173633
Trade/Device Name: VERIFY™ All-in-One STEAM Reusable Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: January 26, 2018
Received: January 29, 2018

Dear 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.

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) or phone (1-800-638-2041 or 301-796-7100).

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)*
K173633

Device Name
VERIFY All-In-One STEAM Reusable Test Pack

Indications for Use *(Describe)*
The VERIFY All-In-One STEAM Reusable Test Pack, when used with a VERIFY Bowie Dick Indicator Strip, is designed for testing the air removal efficiency of pre-vacuum steam sterilizers. The indicator will demonstrate complete dye migration when proper sterilization conditions are met and proper vacuum is achieved. If there is inadequate vacuum such that would result in a 2°C (+1° C/-0°C) temperature difference between the center of the ANSI/AAMI/ISO 11140-5:2007 Standard Test Pack and the drain temperature at the beginning of the final minute of a three and a half minute cycle, the indicator will demonstrate incomplete dye migration (incomplete color change in the indicator window). The test parameters used for validating this device for 134°C for 3.5 minutes with a 2 minute dry time.

VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132° C pre-vacuum steam sterilization cycles utilizing a biological indicator, integrating indicator or both a biological and integrating indicator from the following list.

- 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company
- 3M ATTEST Super Rapid Read Biological Indicators catalog number 1492V manufactured by 3M Company
- Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc.
- Celerity 20 Steam Biological Indicator
- VERIFY STEAM Integrating Indicator

VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132°C pre-vacuum steam sterilization cycles with the VERIFY STEAM Integrating Indicator.

The VERIFY All-In-One STEAM Resuable Test Pack employing the All-in-One PV10 Assembly (a disposable polypropylene sleeve assembly) with a 3M ATTEST Rapid Readout Biological Indicator catalog number 1292 can be used for routine monitoring of 10-Minute 270°F/132°C pre-vacuum steam sterilization cycles. The polypropylene sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Resuable Test Pack.

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™ All-in-One STEAM Reusable Test Pack

Sponsor Facility

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Manufacturing Facility

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Submission Date: February 21, 2018

Premarket Notification Number: K173633

1. Device Name

Trade Name:	VERIFY™ All-in-One STEAM Reusable Test Pack
Common/usual Name:	Biological Indicator Challenge Pack
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

2. Predicate Device

K133267 Dana Reusable Test Pack

3. Description of Device

The VERIFY All-in-One STEAM Reusable Test Pack (formerly identified as the Dana Reusable Test Pack) consists of a reusable aluminum tube with a tortuous path challenge for air removal and steam penetration. The VERIFY All-in-One STEAM Reusable Test Pack will be used with the Celerity 20 Steam Biological Indicator (subject of a separate, concurrent 510(k) premarket notification) with or without the VERIFY STEAM Integrating Integrator (cleared under K152630).

The Celerity 20 Steam Biological Indicator monitors the critical parameters of steam sterilization cycles by producing an optical change (signal) that is detected by the STERIS proprietary reader, Celerity Steam Incubator in 20 minutes to confirm viability of the biological indicator at the end of a steam sterilization process. Both the Celerity 20 Steam Biological Indicator and Incubator are subjects of separate 510(k) premarket notifications.

The VERIFY STEAM Integrating Integrator (cleared in K152630) is a single use device used by healthcare providers to monitor steam sterilization cycles. The VERIFY STEAM Integrating Integrator may be included in the pack and processed according to the pack's instructions for use.

The user will place the assembled VERIFY All-in-One STEAM Reusable Test Pack containing the Celerity 20 Steam Biological Indicator with or without the VERIFY STEAM Integrating Integrator into the sterilizer chamber and perform a 4-minute 270°F pre-vacuum steam sterilization cycle.

At the end of the cycle, the user will remove the Celerity 20 Steam Biological Indicator and the VERIFY STEAM Integrating Integrator from the pack. The Celerity 20 Steam Biological Indicator can either be immediately activated or held at room temperature for a maximum of 72 hours (3 days) prior to activation by twisting the cap and thus puncturing the cap to release the contained media. The

activated BI is incubated at 55-60°C in the Celerity Steam Incubator for a final determination of viability within 20 minutes of incubation.

The VERIFY STEAM Integrating Integrator will be evaluated for a passing or failing result by observing the dark bar of the device. If the dark bar enters the ACCEPT (OK) window, the integrator is read as a PASS. If the dark bar on the device does not enter the ACCEPT (OK), the integrator is read as a FAIL.

4. Intended Use/ Indications for Use

The VERIFY All-In-One STEAM Reusable Test Pack, when used with a VERIFY Bowie Dick Indicator Strip, is designed for testing the air removal efficiency of pre-vacuum steam sterilizers. The indicator will demonstrate complete dye migration when proper sterilization conditions are met and proper vacuum is achieved. If there is inadequate vacuum such that would result in a 2°C (+1°C/-0°C) temperature difference between the center of the ANSI/AAMI/ISO 1140-5:2007 Standard Test Pack and the drain temperature at the beginning of the final minute of a three and a half minute cycle, the indicator will demonstrate incomplete dye migration (incomplete color change in the indicator window). The test parameters used for validating this device for 134°C for 3.5 minutes with a 2 minute dry time.

VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132°C pre-vacuum steam sterilization cycles utilizing a biological indicator, integrating indicator or both a biological and integrating indicator from the following list.

- 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company
- 3M ATTEST Super Rapid Read Biological Indicators catalog number 1492V manufactured by 3M Company
- Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc.
- Celerity 20 Steam Biological Indicator
- VERIFY STEAM Integrating Indicator

VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132°C pre-vacuum steam sterilization cycles with the VERIFY STEAM Integrating Indicator.

The VERIFY All-In-One STEAM Reusable Test Pack employing the All-in-One PV10 Assembly (a disposable polypropylene sleeve assembly) with a 3M ATTEST Rapid Readout Biological Indicator catalog number 1292 can be used for routine

monitoring of 10-Minute 270°F/132°C pre-vacuum steam sterilization cycles. The polypropylene sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Reusable Test Pack.

5. Summary of Technical Characteristics

A comparison of technical characteristics are summarized in **Table 5-1**.

Table 5-1 Summary of pack Physical Description and Technological Properties

Feature	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Dana Reusable Test Pack (K133267)	Comparison
Intended Use / Indication for Use	The VERIFY All-In-One STEAM Reusable Test Pack, when used with a VERIFY Bowie Dick Indicator Strip, is designed for testing the air removal efficiency of pre-vacuum steam sterilizers. The indicator will demonstrate complete dye migration when proper sterilization conditions are met and proper vacuum is achieved. If there is inadequate vacuum such that would result in a 2°C (+1°C/-0°C) temperature difference between the center of the ANSI/AAMI/ISO 1140-5:2007 Standard Test Pack and the drain temperature at the beginning of the final minute of a three and a half minute cycle, the indicator will demonstrate incomplete dye migration (incomplete color change in the indicator window). The test parameters used for validating this device for 134°C for 3.5 minutes with a 2 minute dry time. VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge steam sterilization process in	The Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with a 3M Attest Super Rapid Readout Biological Indicator 1492V along with or without SteriScan Integrators.	The proposed and predicate devices are identical. The current premarket notification is to add the use of the Celerity 20 Steam Biological Indicator (submitted in a separate, concurrent premarket notification) in the VERIFY All-In-One STEAM Reusable Test Pack. The following claims for use of the VERIFY All-In-One Reusable Test Pack have been previously cleared: Bowie Dick Indicator when used with the VERIFY Bowie Dick Indicator Strip (K120592) Routine Monitoring of a 4-minute 270°F/132°C pre-vacuum steam sterilization cycle when used with: • 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company (K092944) • Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc. (K130135)

Feature	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Dana Reusable Test Pack (K133267)	Comparison
	healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132°C pre-vacuum steam sterilization cycles utilizing a biological indicator, integrating indicator or both a biological and integrating indicator from the following list. • 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company • 3M ATTEST Super Rapid Read Biological Indicators catalog number 1492V manufactured by 3M Company • Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc. • Celerity 20 Steam Biological Indicator • VERIFY STEAM Integrating Indicator VERIFY All-In-One STEAM Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4-minute 270°F/132°C pre-vacuum steam sterilization cycles with the VERIFY		• VERIFY STEAM Integrating Indicator (K102761) Routine Monitoring of a 10-minute 270°F/132°C pre-vacuum steam sterilization cycle when used with the additional polypropylene sleeve assembly and the 3M ATTEST Rapid Readout Biological Indicator catalog number 1292 (K103321) NOTE: In previous submissions, the VERIFY All-In-One STEAM Reusable Pack was referred to as the Dana Reusable Test Pack and the VERIFY STEAM Integrating Integrator was called the SteriScan Integrator.

Feature	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Dana Reusable Test Pack (K133267)	Comparison
	STEAM Integrating Indicator. The VERIFY All-In-One STEAM Reusable Test Pack employing the All-in-One PV10 Assembly (a disposable polypropylene sleeve assembly) with a 3M ATTEST Rapid Readout Biological Indicator catalog number 1292 can be used for routine monitoring of 10-Minute 270°F/132°C pre-vacuum steam sterilization cycles. The polypropylene sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Reusable Test Pack.		
General Design	Aluminum chamber that can be sealed at one end using a removable aluminum plug. The other end has a permanently pressed in aluminum cap with a precision machined spiral that provides a tortuous path for air removal. The aluminum chamber is large enough to contain a biological indicator and chemical indicator.	Aluminum chamber that can be sealed at one end using a removable aluminum plug. The other end has a permanently pressed in aluminum cap with a precision machined spiral that provides a tortuous path for air removal. The aluminum chamber is large enough to contain a biological indicator and chemical indicator.	Identical configuration

Feature	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Dana Reusable Test Pack (K133267)	Comparison
Biological Indicator	• 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company • 3M ATTEST Super Rapid Read Biological Indicators catalog number 1492V manufactured by 3M Company • Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc. • Celerity 20 Steam Biological Indicator	3M ATTEST Super Rapid Read Biological Indicators catalog number 1492V manufactured by 3M Company	The proposed and predicate devices are identical. The current premarket notification is to add the use of the Celerity 20 Steam Biological Indicator (submitted in a separate, concurrent premarket notification) in the VERIFY All-In-One STEAM Reusable Test Pack. The following BIs were cleared in previous submissions: • 3M ATTEST Rapid Read Biological Indicators catalog number 1292 manufactured by 3M Company (K092944) • Smart-Read EZTest Self Contained Biological Indicators for steam manufactured by MesaLabs, Inc. (K130135)
Chemical Indicator	VERIFY STEAM Integrating Indicator	VERIFY STEAM Integrating Indicator (previously branded as the Steriscan Integrating Integrator)	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
Simulated Use	Performance of the BI in the Reusable Test Pack is equivalent to the performance of the BI in the AAMI 16 towel test pack.	PASS
	Performance of the chemical integrator in the Reusable Test Pack is equivalent to the performance of the chemical integrator in the AAMI 16 towel test pack.	PASS
	Reusable Test Pack provides an equivalent or greater challenge than the AAMI 16 towel test pack.	PASS
BI in pack vs BI outside of pack	Reusable Test Pack provides a greater challenge to the process than the BI itself.	PASS

Test	Acceptance Criteria	Conclusion
CI in pack vs CI outside of pack	Reusable Test Pack provides a greater challenge to the process than the integrator by itself.	PASS

7. Conclusion

The VERIFY All-in-One STEAM Reusable Test Pack has met the established performance criteria. Based on the conclusions drawn from the intended use, technological characteristics and nonclinical tests demonstrate that the subject device is as safe, as effective, and performs at least as well as the legally marketed predicate device, Dana Reusable Test Pack cleared in K133267 Class II (21 CFR 880.2800, Product code FRC).