



November 20, 2018

Steris Corporations
Jennifer Nalepka
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K182931

Trade/Device Name: VERIFY All-In-One STEAM Reusable Test Pack, VERIFY All-In-One STEAM Reusable Test Pack with Step Counter, VERIFY All-In-One STEAM Reusable Test Pack with Tracker Tag

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization Process Indicator

Regulatory Class: Class II

Product Code: FRC

Dated: October 19, 2018

Received: October 22, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Elizabeth F. Claverie -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

Indications for Use

510(k) Number (if known)

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 were 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 SixCess MF4 STEAM Emulating 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.

The VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly with a Celerity 20 STEAM Biological Indicator and a Celerity 10 STEAM Chemical Indicator can be used for routine monitoring of 10-minute 270°F/132°C dynamic air removal steam sterilization cycles. The sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Reusable 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

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

Manufacturing Facility

STERIS Corporation
Franklin Park Facility
11457 Melrose Ave.
Franklin Park, IL 60131
Phone: (847) 455-2881

Contact: Jennifer Nalepka
Senior Regulatory Affairs Specialist

Telephone: (440) 392-7458
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Submission Date: October 19, 2018

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
VERIFY™ All-in-One STEAM Reusable Test Pack

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

K173633 VERIFY All-in-One STEAM Reusable Test Pack

3. Description of Device

The VERIFY All-in-One STEAM 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 Xtend 10 Assembly containing the Celerity 20 STEAM Biological Indicator and the Celerity 10 STEAM Chemical Indicator.

The Celerity Xtend 10 Assembly consists of a tube and cap design, comprised of one (1) polypropylene tube and one (1) silicone rubber cap containing one (1) Celerity 20 STEAM Biological Indicator and one (1) Celerity 10 STEAM Chemical Indicator and can only be used with the VERIFY All-in-One STEAM Reusable Test Pack. The Celerity Xtend 10 Assembly has a tamper evident seal that will be broken once the assembly has been opened after use. A broken tamper evident seal will indicate to the user that it cannot be reused. The Celerity Xtend 10 Assembly is a single use device used for routine monitoring of 10-minute 270°F 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.

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 has been cleared under K173634 and K181429 and the Incubator has been cleared under K173670.

The Celerity 10 STEAM Chemical Indicator is a single-use device used to monitor a 10-minute 270°F/132°C dynamic air removal steam sterilization cycle and is subject of a concurrent premarket notification.

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION

VERIFY™ All-in-One STEAM Reusable Test Pack

The user will place the Celerity Xtend 10 Assembly inside the VERIFY All-in-One STEAM Reusable Test Pack and screw on the lid. The user will place the VERIFY All-in-One STEAM Reusable Test Pack into the sterilizer chamber and perform a 10-minute 270°F dynamic air removal steam sterilization cycle.

At the end of the cycle, the user will remove the Celerity Xtend 10 Assembly from the pack. The Celerity 10 STEAM Chemical Indicator can be evaluated for a pass or fail prior to opening the assembly. The Celerity 10 STEAM Chemical Indicator indicates a pass by a color change of yellow to blue/purple. If there is no color change or an incomplete color change, the Celerity 10 STEAM Chemical Indicator indicates a fail.

If the CI indicates a pass, 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.

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 were 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.

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VERIFY™ All-in-One STEAM Reusable Test Pack

- Celerity 20 STEAM Biological Indicator
- VERIFY STEAM Integrating Indicator
- VERIFY SixCess MF4 STEAM Emulating 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.

The VERIFY All-in-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly with a Celerity 20 STEAM Biological Indicator and a Celerity 10 STEAM Chemical Indicator can be used for routine monitoring of 10-Minute 270°F/132°C dynamic air removal steam sterilization cycles. The sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Reusable Test Pack.

5. Technical Characteristics Comparison Table

A comparison of technical characteristics are summarized in **Table 6-1**.

Table 6-1 Summary of pack Physical Description and Technological Properties

Feature	VERIFY All-In-One STEAM Reusable Test Pack (proposed)	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	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	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	The proposed and predicate devices are identical. The current premarket notification is to add the use of the Celerity 10 Xtend Assembly for routine monitoring and qualification of 10-minute 270°F/132°C prevacuum steam sterilization cycles in the VERIFY All-In-One STEAM Reusable Test Pack.

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
VERIFY™ All-in-One STEAM Reusable Test Pack

Feature	VERIFY All-In-One <u>STEAM</u> Reusable Test Pack (proposed)	VERIFY All-In-One <u>STEAM</u> Reusable Test Pack (K173633)	Comparison
	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 were 134°C for 3.5 minutes with a 2 minute dry time. VERIFY All-In-One <u>STEAM</u> 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	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 were 134°C for 3.5 minutes with a 2 minute dry time. VERIFY All-In-One <u>STEAM</u> 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	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) • VERIFY <u>STEAM</u> Integrating Indicator (K102761) • Celerity 20 <u>STEAM</u> Biological Indicator (K173633) • VERIFY SixCess MF4 <u>STEAM</u> Emulating Indicator (K110253) ◦ The VERIFY SixCess MF4 <u>STEAM</u> Emulating Indicator was inadvertently left out of the Indications for Use in the previous clearance for the Reusable Test Pack due to a typographical error. 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

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
VERIFY™ All-in-One STEAM Reusable Test Pack

Feature	VERIFY All-In-One STEAM Reusable Test Pack (proposed)	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Comparison
	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 SixCess MF4 STEAM Emulating 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.	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.	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, the VERIFY STEAM Integrating Integrator was called the SteriScan Integrator and the VERIFY SixCess MF4 STEAM Emulating Indicator was called the Dana Emulating Indicator.

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
VERIFY™ All-in-One STEAM Reusable Test Pack

Feature	VERIFY All-In-One STEAM Reusable Test Pack (proposed)	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	Comparison
	The VERIFY All-in-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly with a Celerity 20 STEAM Biological Indicator and a Celerity 10 STEAM Chemical Indicator can be used for routine monitoring of 10-Minute 270°F/132°C pre-vacuum steam sterilization cycles. The 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

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
VERIFY™ All-in-One STEAM Reusable Test Pack

Feature	VERIFY All-In-One STEAM Reusable Test Pack (proposed)	VERIFY All-In-One STEAM Reusable Test Pack (K173633)	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 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	Identical
Chemical Indicator	VERIFY STEAM Integrating Indicator	VERIFY STEAM Integrating Indicator	Identical
Extended Cycle Assemblies	- PV10 Assembly with a 3M ATTEST Rapid Readout Biological Indicator catalog number 1292 - Celerity Xtend 10 Assembly containing a Celerity 20 STEAM Biological Indicator and Celerity 10 STEAM Chemical Indicator	PV10 Assembly with a 3M ATTEST Rapid Readout Biological Indicator catalog number 1292	The proposed and predicate devices are identical. The current premarket notification is to add the use of the Celerity 10 Xtend Assembly for routine monitoring and qualification of 10-minute 270°F/132°C prevacuum steam sterilization cycles in the VERIFY All-In-One STEAM Reusable Test Pack.

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 6-2** below.

Table 6-2. 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 predicate	PASS
Celerity Xtend 10 Assembly in pack vs Celerity Xtend 10 Assembly outside of pack	Reusable Test Pack containing the Celerity Xtend 10 Assembly provides a greater challenge to the process than the Celerity Xtend 10 Assembly 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 as well as or better than the legally marketed predicate device (21 CFR 880.2800, Product code FRC).