October 28, 2026

STERIS
Anthony Piotrkowski
Senior Director, Regulatory Affairs
5960 Heisley Rd.
Mentor, Ohio 44046

Re: K260822
Trade/Device Name: VERIFY® RESI-TEST™ SWAB Protein Detection Indicator
Regulation Number: 21 CFR 880.6930
Regulation Number: Qualitative Cleaning Process Protein Indicator
Regulatory Class: Class II
Product Code: SDC
Dated: March 13, 2026
Received: March 13, 2026

Dear Anthony Piotrkowski:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KATHARINE SEGARS -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260822

Device Name
VERIFY® RESI-TEST™ SWAB Protein Detection Indicator

Indications for Use *(Describe)*
The VERIFY® RESI-TEST™ SWAB Protein Detection Indicator is a qualitative protein detection test used on a medical device surface to detect the presence of residual protein in the extracted soils from the swab after cleaning and prior to high level disinfection or sterilization. This is assessed through a solution color change to any blue coloration when compared to the start color. The indicator color change may become more vibrant when exposed to higher levels of residual protein soils in the extract.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
For
VERIFY® RESI-TEST™ SWAB Protein Detection Indicator

Sponsor Facility

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

Contact: Anthony Piotrkowski
Senior Director, Regulatory Affairs

Telephone: (440) 667-8479
e-mail: tony_piotrkowski@steris.com

Submission Date: October 28, 2026
510(k) Number: K260822

1. Device Name

Trade Name:	VERIFY® RESI-TEST™ SWAB Protein Detection Indicator
Classification Name:	Qualitative cleaning process protein indicators
Classification	21 CFR 880.6930
Class	II
Product Code	SDC

2. Predicate Device

VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP), DEN230085

3. Description of Device

The VERIFY® RESI-TEST™ SWAB Protein Detection Indicator is intended to detect residual protein on surfaces of cleaned medical devices. The product is intended to detect the presence of residual protein in the extracted soils from the swab after cleaning and prior to high level disinfection or sterilization.

4. Intended Use/ Indications for Use

The VERIFY® RESI-TEST™ SWAB Protein Detection Indicator is a qualitative protein detection test used on a medical device surface to detect the presence of residual protein in the extracted soils from the swab after cleaning and prior to high level disinfection or sterilization. This is assessed through a solution color change to any blue coloration when compared to the start color. The indicator color change may become more vibrant when exposed to higher levels of residual protein soils in the extract.

5. Summary of Technical Characteristics

A comparison of the subject and predicate device technical characteristics are summarized below in **Table 1**.

Table 1. Summary Physical Description and Technological Properties

Feature	VERIFY™ RESI-TEST™ SLIDE-THRU CPP (DEN230085)	VERIFY RESI-TEST SWAB Protein Detection Indicator (proposed)	Comparison
Intended Use / Indications for Use	The VERIFY RESI-TEST SLIDE-THRU Cleaning Process Protein (CPP) Indicator is a qualitative protein detection test used on a medical device brushable lumen to detect the presence of residual protein in the extracted soils from the brush after cleaning and prior to high level disinfection or sterilization. This is assessed through any solution color change from brown/tan to green/gray/blue. The indicator may become more blue when exposed to higher levels of residual protein soils in the extract. Use only with	The VERIFY® RESI-TEST™ SWAB Protein Detection Indicator is a qualitative protein detection test used on a medical device surface to detect the presence of residual protein in the extracted soils from the swab after cleaning and prior to high level disinfection or sterilization. This is assessed through a solution color change to any blue coloration when compared to the start color. The indicator color change may become more vibrant when exposed to higher	Similar – both products are designed to sample and detect residual protein on cleaned devices through a color change

Feature	VERIFY™ RESI-TEST™ SLIDE-THRU CPP (DEN230085)	VERIFY RESI-TEST SWAB Protein Detection Indicator (proposed)	Comparison
	VERIFY RESI-TEST SLIDE-THRU Brush (sold separately) for the lumen size range, as shown below: - Large brush: 2.8-5.0 mm / 290 cm length - Medium brush: 1.5-2.6 mm / 220 cm length - Small brush: 1.0-1.2mm / 150 cm length.	levels of residual protein soils in the extract.	
Basis for detection	Bradford Colorimetric Protein Assay	Bradford Colorimetric Protein Assay	Same
Color change	Brown/tan to green/gray/blue	Brown/tan to green/gray/blue	Same
Shelf-life	12 months (refrigerated storage)	12 months (room temperature storage)	Same duration, the different storage temperature was evaluated through testing
Sensitivity	Detects below 6.4 µg/cm^2	Detects below 6.4 µg/cm^2	Same

6. Summary of Non-clinical Tests

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

Table 2. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
Simulated Use	Product must detect clinically relevant levels of protein on a wide variety of medical devices, soiled under worst-case conditions.	PASS
Swab Integrity Testing	Product must not leave behind lint or residues on sampled devices	PASS
Shelf-life	Product must demonstrate suitable performance throughout its labeled shelf-life	PASS
Biocompatibility	Product must be non-cytotoxic	PASS
Use Life Stability of Read	Results must remain unchanged for at least 1 hour throughout shelf-life.	PASS
Spectrometer Test	Product must show distinct, readable color difference between 0, 1 and 5 µg of protein	PASS
Human Factors	Users can correctly identify pass and fail samples	PASS

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device (DEN230085, Class II (21 CFR 880.6930), product code SDC.