DE NOVO CLASSIFICATION REQUEST FOR

VERIFY™ RESI-TEST™ SLIDE THRU CLEANING PROCESS PROTEIN (CPP) INDICATOR

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Qualitative cleaning process protein indicator.** A qualitative cleaning process protein indicator is intended for use by a health care provider on a cleaned medical device as an interim step prior to high level disinfection or sterilization of the cleaned medical device. The intended use is to inform the health care user of the presence of residual soil protein in the sample extract.

NEW REGULATION NUMBER: 21 CFR 880.6930

CLASSIFICATION: Class II

PRODUCT CODE: SDC

BACKGROUND

DEVICE NAME: VERIFY™ RESI-TEST™ SLIDE THRU Cleaning Process Protein (CPP) Indicator

SUBMISSION NUMBER: DEN230085

DATE DE NOVO RECEIVED: December 18, 2023

SPONSOR INFORMATION:

STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

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 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.

LIMITATIONS

The VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator is intended to be marketed for Over-The-Counter (OTC) use.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The VERIFY™ RESI-TEST™ SLIDE THRU Cleaning Process Protein (CPP) Indicator is a protein detection indicator designed for use in a health care facility's reprocessing department. The VERIFY™ RESI-TEST™ SLIDE THRU CPP is used to assess the cleaned brushable medical device lumens for the presence of residual protein in the extracted soil from the brush before further processing (high level disinfection or sterilization). The VERIFY™ RESI-TEST™ SLIDE THRU CPP is provided as a kit consisting of a solution that changes color in the presence of protein, a protein standard and reaction vials. The VERIFY™ RESI-TEST™ SLIDE THRU CPP Indicator is designed to be used with endoscope brushes (provided separately). The dedicated brushes come in three different sizes to accommodate testing of different sized lumens (1.0 -1.2 mm, 1.5 - 2.6 mm and 2.8 - 5.0 mm).

For use, the brushes are wetted and passed through the lumens (1 brush for each lumen) of a cleaned device to sample the lumen's interior surface. The brush is then bathed in the protein detection solution and the user observes the solution for color change from brown/tan to green/gray/blue to identify if protein is present on the brush.

Table 1. Device components

Product Number	Description	Lumen Size Range
LCC101	VERIFY RESI-TEST SLIDE-THRU CPP Indicator	N/A
2D79QH	Large VERIFY RESI-TEST SLIDE-THRU Brush	2.8-5.0 mm / 290 cm length
2D74QH	Medium VERIFY RESI-TEST SLIDE-THRU Brush	1.5-2.6 mm / 220 cm length
2D73QH	Small VERIFY RESI-TEST SLIDE-THRU Brush	1.0-1.2mm / 150 cm length

Principles of Operation:
The VERIFY™ RESI-TEST™ CPP Indicator is a colorimetric protein assay and is not designed to be quantitative. There are currently no consensus standards or industry guidelines that identify the maximum amount of protein allowed on a surface to still be considered clean.

Figure 1. Reference of the Resi-Test Reagent color reaction at different protein levels

Start color / no protein detected

Examples of color change when protein detected

SUMMARY OF BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The VERIFY™ RESI-TEST™ SLIDE THRU Cleaning Process Protein (CPP) Indicator is provided non-sterile and does not require additional reprocessing or sterilization. The device is intended for single use.

The VERIFY™ RESI-TEST™ SLIDE THRU Cleaning Process Protein (CPP) Indicator has a labeled expiration of 12 months when stored refrigerated or 30 days when stored at room temperature. The sponsor provided adequate stability testing supporting the claimed shelf life.

BIOCOMPATIBILITY

The materials of construction of the VERIFY™ RESI-TEST™ SLIDE THRU Cleaning Process Protein (CPP) Indicator have limited contact with users and do not directly contact patients. The user is instructed to wear appropriate personal protective equipment (PPE), including gloves, during use of the device, which reduces the risk of contact with the materials of construction.

The patient is indirectly exposed to materials only if linting (fragmentation of the sampling portion) of the brush occurs during use. The sampling portion of the device are moistened prior to sampling, thus reducing the probability of linting. Sampled devices are further processed (by disinfection or terminal sterilization) following sampling, which has potential to remove any detached materials. Users are instructed to inspect brushes for damage and the sampled device after sampling which further reduces the risk that materials will remain on/in samples device and subsequently contact a patient.

Table 2. Device Component Contact Classification

Component	Patient Contact	User Contact	Impacts Biocompatibility?
Slide Thru Brushes	Yes, indirect	Yes, direct	Yes
Instrument Solution Vial	No	Yes, direct	Yes
Packaging	No	Yes, direct	Yes

The sponsor provided adequate Biological Evaluation Report to support biocompatibility of the device. The sponsor also provided adequate Cytotoxicity testing of the sampling brush, in accordance with ISO 10993-5:2009.

SOFTWARE & CYBERSECURITY

The device does not use software/firmware.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

There device is not electrical. The device does not contain battery. The device is not wall powered.

PERFORMANCE TESTING – BENCH

There is no clinical performance test for the device.

The subject device is analogous to the process monitor in that it provides a binary result indicating the presence of protein – it does not indicate a clean device. The assessment of the subject device performance was therefore conducted based on a level of evidence appropriate to support the qualitive cleaning process protein indicator claim. The level of evidence requested and received in support of this intended use is adequate and in line with precedent established for devices in infection control space.

The sponsor conducted the following non-clinical performance tests to support the device achieves its intended use:

☐ **Use Life Stability Testing**

The sponsor conducted a use life stability validation study to assess the performance of the ResiTEST solution in an illuminated environment under normal working conditions:

- Test results for ResiTEST solution with sterile water (50 µL) indicated pass for all samples at 10 min, 30 min, and 60 min test time points post-acclimatization. Color read time was ≤ 1 second; no color change observed at 10 seconds. These studies were performed for capped vials, uncapped vials (max 30 min) then resealed, and uncapped vials. The results demonstrated stability of the ResiTEST solution during use.
- Test results for ResiTEST solution inoculated with the protein standard (50 µg, dried) indicated pass for all samples at 10 min, 30 min, and 60 min test time points post-acclimatization. A desirable color change was observed with 1 second read time. These studies were performed for capped vials, uncapped vials (max 30 min) then resealed, and uncapped vials. The results demonstrated stability of the ResiTEST solution and the protein standard (50 µg, dried) during use.

- Test results for ResiTEST solution and Bovine Serum Albumin (BSA) inoculated slide indicated pass for all samples at 10 min, 30 min, and 60 min test time points post-acclimatization. A color change was observed with 10 second read time. These studies were performed for capped vials, uncapped vials (max 30 min) then resealed, and uncapped vials. The results demonstrated stability of the ResiTEST solution in its ability to detect protein.

In the above three test cases, all samples post-testing were exposed further to light between 3 – 6 hours. Results indicated no change in color or intensity from the recorded results after 1 hour and 3 hours. The Instructions for Use directs the user to observe and record color of the solution 10 seconds after agitation of the disc end of the brush in the solution vial.

☐ **Spectrometer Testing**

The sponsor provided UV/Vis absorption spectroscopy testing of samples from three different lots. The ResiTEST solution of the subject device was analyzed on a UV/Vis spectrophotometer over the wavelength range from 320 nm to 900 nm for the neat solution (no protein added) and solution dosed with (b) (4) and (b) (4) protein standard (Bovine Serum Albumin), all at triplicates. The qualitative test results demonstrated absorption profile changes in the presence of protein: changes in relative abundance of absorption peaks at wavelengths specific to the proprietary protein assay. These test results support color transition from brown/tan (no protein added) to blue ((b) (4) protein) and more blue ((b) (4) protein).

☐ **Simulated Use Testing**

The sponsor provided two types of simulated use testing:

- Polytetrafluoroethylene (PTFE) lumens of 1 meter length: sponsor demonstrated the proposed device can detect presence of a protein standard, Bovine Serum Albumin, from PTFE lumens of 1 meter length of six different diameters, inoculated at 6.4 µg/cm^2 and 1 µg/cm^2 (mass of protein per the internal surface area of the lumen). All lumens were straight geometry. The study results are qualitative and are described as gray color, light-blue color, and blue color. Test results from all protein inoculated PTFE lumens indicated a color change (residual protein detected). The test results demonstrate the subject device can qualitatively detect presence of residual protein in PTFE lumens of 1 meter length at soil levels as low at 1 µg/cm^2.

- Brushable lumens of Endoscopes: The sponsor provided adequate simulated use testing that included:
  - a range of endoscopes with features that adequately presented a challenge for the sampling brush component of the subject device;
    - All endoscopes had history of multiple types of feasibility and validation testing studies over the years and have undergone ≥ 6 cycles of reprocessing.

        - The range of endoscopes represented different lumen dimensions and materials.
    - artificial soil that adequately represented the soil type encountered in clinical use across various endoscope models;
    - positive and negative controls for the subject device;
    - soiling of the brushable lumens of the endoscopes at protein levels both above and below the cleaning validation threshold;
    - three consecutive trials at each protein soil level:
        - baseline testing of the lumen after cleaning indicated no color change (did not detect residual protein in the extracted soil from the brush);
        - testing of the lumen after soiling at protein levels below and above the cleaning validation threshold indicated a color change to green/gray/blue (indicative of residual protein).

This simulated use test results indicated the protein assay of the subject device is sensitive to detect presence of residual protein in all tested lumens of endoscopes soiled at protein levels below and above the cleaning validation threshold. After cleaning the endoscopes, the tested lumens indicated no color change (no residual protein detected).

☐ **Brush Integrity Testing**

The sponsor stated each batch of the sampling brush is integrity tested as part of quality control at the manufacturer. The sponsor provided an example quality control test result. The Instructions for Use instructs the health care users to use the sampling brush only on lumens that can be brushed per the medical device manufacturer's instructions. Additionally, the sponsor included brush integrity as another endpoint, in their simulated use testing. The simulated use test results indicated the sampling brush maintained integrity after each use.

☐ **Human Factor Assessment**

Human factors testing was deemed not required based on the evaluation of probable risks and the anticipated level of user interface needed to support the use of the device. Also, the sponsor included a warning statement in the labeling, recommending conducting an Ishihara Test for Color Blindness prior to health care users interpreting the test results.

LABELING

The labeling consists of the packaging label and the Instructions for Use.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a qualitative cleaning process protein indicator and the measures necessary to mitigate these risks.

Risks to Health	Mitigation Measures
Adverse tissue reaction	Non-clinical performance testing Biocompatibility evaluation Labeling
Inaccurate interpretation of test results leading to infection from inadequately cleaned medical device surfaces or delay of treatment	Non-clinical performance testing Shelf-life testing Labeling
Damage to cleaned medical device leading to infection from inadequately cleaned medical device surfaces or delay of treatment.	Non-clinical performance testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the qualitative cleaning process protein indicator device is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) For cleaning process protein indicator devices with mechanical components and/or accessories, functional testing of these components and accessories must demonstrate maintenance of functional integrity for the intended use;
   (ii) Compatibility with cleaned medical devices;
   (iii) Simulated use test must evaluate the cleaning process protein indicator device performance on a cleaned medical device under worst-case conditions. If simulated use testing cannot represent the worst-case clinical use condition, then in-use test must demonstrate the device performs as intended per indications for use with clinically used medical devices, under worst-case conditions; and
   (iv) Stability test must demonstrate the device performs in accordance with the device indications for use and instruction for use for the claimed shelf life under the labeled storage conditions.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) The labeling must include:
   (i) A statement specifying the types of health care users that can use the cleaning process protein indicator device;
   (ii) Instructions for observation and interpretation of qualitative test results, including

any limitations;
(iii) Instructions that the use of the cleaning process protein indicator device should not alter implementation of the cleaned medical device manufacturer's validated reprocessing instructions;
(iv) Stability of test results;
(v) Cleaned medical device compatibility and incompatibility information;
(vi) Instructions for personal protective equipment to be used with the device; and
(vii) A shelf-life.

BENEFIT-RISK DETERMINATION

Benefit:

The sponsor demonstrated that the probable benefits include the following:

The subject device is a novel tool available for use during reprocessing of medical devices in health care settings to test for the presence of residual protein in extracted soil. The device informs the health care user of the presence of protein containing debris in the sampled lumens of medical devices after cleaning and prior to high-level disinfection or sterilization. Based on the health care facility's internal policy, the health care user may choose to re-clean a device after protein detection in the extracted soil from the brush. The sponsor's simulated use test results support the above probable benefits: for each tested brushable lumen of endoscopes, the sponsor conducted three consecutive trials at each protein soil level. Following soiling and testing (results show color change), the sponsor cleaned the tested endoscope per the endoscope manufacturer's validated cleaning instructions. Test results from all cleaned endoscope lumens indicated result of 'no color change' (no residual protein detected).

Risks:

The main probable risk of the device is needless re-cleaning of a medical device which may delay use of the reusable device for patient treatment. It may also introduce excessive scratches and dents that may increase soil retention and may prevent effective complete cleaning using validated procedures and increase the risk of cross-contamination and patient infection. Another probable risk is the device may give the end user false confidence the tested medical device is clean if the device cannot achieve its intended use, leading to inadequate cleaning and cross-contamination, which may lead to patient infection. These probable risks all have been mitigated through completion of risk mitigation measures outlined in the Risk to Health table. Furthermore, the labeling of the reusable medical devices themselves instruct the health care users to clean, visually inspect, and high-level disinfect or sterilize the medical devices following the manufacturer's FDA-approved validated process. The subject device is intended for use as an interim step after cleaning and prior to high-level disinfection or sterilization.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the testing provided and available information summarized above, for the following indication statement:

> *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 VERIFY RESI-TEST SLIDE-THRU Brush (sold separately) for the lumen size range, as shown below:*
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> *- 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.*

The probable benefits outweigh the probable risks for the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator is granted and the device is classified as follows:

Product Code: SDC
Device Type: Qualitative cleaning process protein indicator
Regulation Number: 21 CFR 880.6930
Classification: Class II