November 12, 2024

Steris Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: DEN230085
Trade/Device Name: VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator
Regulation Number: 21 CFR 880.6930
Regulation Name: Qualitative cleaning process protein indicator
Regulatory Class: Class II
Product Code: SDC
Dated: December 18, 2023
Received: December 18, 2023

Dear Anthony Piotrkowski:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator, an over-the-counter device under 21 CFR Part 801 Subpart Cwith the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator, and substantially equivalent devices of this generic type, into Class II under the generic name qualitative cleaning process protein indicator.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 18, 2023, FDA received your De Novo requesting classification of the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the VERIFY™ RESI-TEST™ SLIDE-THRU Cleaning Process Protein (CPP) Indicator can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the qualitative cleaning process protein indicator they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 FD & C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Nahid Ilyas at 240-402-9754.

Sincerely,

Binita S. Ashar -S

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Director
OHT4: Office of Surgical and
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