May 1, 2026

Steris
Steve Elliott
Senior Manager, Regulatory Affairs
5960 Heisley Rd.
Mento, Ohio 44060-1834

Re: DEN240075
Trade/Device Name: Prolystica Pass Thru Disinfectant Wipes
Regulation Number: 21 CFR 880.6891
Regulation Name: Interim reprocessing cleaning and intermediate-level disinfection wipe
Regulatory Class: Class II
Product Code: SHM
Dated: December 12, 2024
Received: December 12, 2024

Dear Steve Elliott:

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 Prolystica Pass Thru Disinfectant Wipes, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> Prolystica Pass Thru Disinfectant Wipes are a ready-to-use (RTU) one-step cleaner and intermediate level disinfectant. They are intended for use in hospitals and other healthcare facilities to clean and intermediate level disinfect non-submersible and/or heat-sensitive critical and semi-critical medical devices or medical device components. When properly used, the medical device will be intermediate level disinfected and rendered "safe to handle".
>
> Not intended for use on flexible endoscopes.
> Not intended for use as a terminal sterilization or high-level disinfection (HLD) processing step for critical and semi-critical devices.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Prolystica Pass Thru Disinfectant Wipes, and substantially equivalent devices of this generic type, into Class II under the generic name interim reprocessing cleaning and intermediate-level disinfection wipe.

FDA identifies this generic type of device as:

> **Interim reprocessing cleaning and intermediate-level disinfection wipe**. An interim reprocessing cleaning and intermediate-level disinfection wipe is intended for use by a health care provider to clean and intermediate-level disinfect medical device types indicated on the labeling as an interim

step prior to sterilization or high-level disinfection. This is intended as a non-terminal disinfection step compatible with subsequent terminal reprocessing such as sterilization or high-level disinfection and renders the device safe to handle by the user compared to unprocessed, clinically soiled devices.

"Safe to handle" is limited in scope to mean the device has been appropriately intermediate-level disinfected.

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 12, 2024, FDA received your De Novo requesting classification of the Prolystica Pass Thru Disinfectant Wipes. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prolystica Pass Thru Disinfectant Wipes 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 Prolystica Pass Thru Disinfectant Wipes 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**
Patient infection from exposure to contaminated devices from inadequate cleaning and disinfection due to wipe performance failure, use errors or wipe induced contamination	Shelf-life testing Human factors testing Non-clinical performance testing Labeling
User infection from exposure to contaminated devices from inadequate cleaning and disinfection due to wipe performance failure, use errors or wipe induced contamination	Shelf-life testing Human factors testing Non-clinical performance testing Labeling
Device damage from wipe processing	Non-clinical performance testing Labeling

Risks to Health	Mitigation Measures
Patient adverse tissue reaction from device processed with wipes	Biocompatibility evaluation Non-clinical performance testing Labeling
User adverse tissue reaction from wipes	Biocompatibility evaluation Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the interim reprocessing cleaning and intermediate-level disinfection wipe 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 evaluated to ensure device function and integrity during use:
   (i) Cleaning validation testing must demonstrate that the subject device meets the cleaning endpoint by removeing clinically relevant soil from the devices intended for processing with the wipes under worst-case, simulated use conditions;
   (ii) Performance and simulated use testing must demonstrate intermediate-level disinfection for the intended devices using worst-case representative device;
   (iii) Testing must demonstrate the device does not have a negative impact on subsequent reprocessing (sterilization or high-level disinfection);
   (iv) Germicidal activity must be evaluated for the entire claimed shelf life and use life; and
   (v) Device intercompatibility testing must demonstrate that the processed device and materials function as intended after worst-case processing with the wipes.

(2) Devices reprocessed by the subject device must be demonstrated to be biocompatible for the patient.

(3) The interim processing wipe must be demonstrated to be biocompatible for the user.

(4) Human factors evaluation must demonstrate that intended users can correctly use the device, based solely on reading the instructions for use.

(5) Labeling must include:
   (i) Information on devices and materials that can be reprocessed by the subject device;
   (ii) Description of the required preparation for cleaning and disinfection with the subject device;
   (iii) A statement that subject device is not intended to be a terminal reprocessing step;
   (iv) Instructions for personal protective equipment to be used with the device;
   (v) Shelf life and use life information, and appropriate use and storage conditions;
   (vi) Instructions that the use of the subject device should not change or replace the reusable medical device manufacturer's validated reprocessing instructions; and
   (vii) Statement that facility's current standard practices, policies and procedures for handling medical devices following interim processing should determine how to handle a device processed with the interim processing device.

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 interim reprocessing cleaning and intermediate-level disinfection wipe 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 Management System Regulation (QMSR) (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).

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.

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 Lianji Jin at lianji.jin@fda.hhs.gov.

Sincerely,

CHRISTOPHER K. DUGARD -S

Christopher K. Dugard, MS
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