June 2, 2023

Tristel Solutions Limited
℅ Jeffrey Shapiro
Director
Hyman, Phelps, & McNamara, P.C.
700 13th St NW, Suite 1200
Washington, District of Columbia 20005

Re: DEN220041
Trade/Device Name: Tristel Duo ULT
Regulation Number: 21 CFR 880.6886
Regulation Name: Foam or gel chemical sterilant/high level disinfectant
Regulatory Class: Class II
Product Code: QWS
Dated: June 29, 2022
Received: July 13, 2022

Dear Jeffrey Shapiro:

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 Tristel Duo ULT, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Tristel Duo ULT is a high level disinfect foam for reprocessing ultrasound probes. It can be used to high level disinfect endocavity transvaginal and transrectal probes, and skin surface transducers that may contact non-intact skin during use.
>
> Tristel Duo ULT is a high level disinfectant when used in accordance with the directions for use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above Minimum Recommended Concentration (MRC).
>
> Tristel Duo ULT must be applied on the surface of an ultrasound probe using Duo Wipes.
>
> Duo Wipes are intended to apply Tristel Duo ULT foam on the surface of ultrasound probes and to remove residue of the foam after high level disinfection.
>
> Each dose of Tristel Duo ULT foam and each Duo Wipe are single use.
>
> The semi-critical ultrasound probes reprocessed by Tristel Duo ULT must first be cleaned according to a validated cleaning protocol or standard and following the device manufacturers' instructions.
>
> Tristel Duo ULT foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC.
>
> Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel Duo ULT may be verified using Duo Test Strips.

Tristel Duo ULT is intended to be marketed for prescription use.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Tristel Duo ULT, and substantially equivalent devices of this generic type, into Class II under the generic name foam or gel chemical sterilant/high level disinfectant.

FDA identifies this generic type of device as:

> **Foam or gel chemical sterilant/high level disinfectant**. A foam or gel chemical sterilant/high level disinfectant is a germicide in the form of a foam or gel that is intended for use as the terminal step in high level disinfection of medical devices prior to patient use.

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 June 29, 2022, FDA received your De Novo requesting classification of the Tristel Duo ULT. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Tristel Duo ULT 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 Tristel Duo ULT 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:

Identified Risks to Health and Mitigation Measures

| **Identified Risks to Health** | **Mitigation Measures** |
|---|---|
| Patient cross-contamination due to high level disinfectant (HLD) lacking adequate potency on pathogens left on the surface of the disinfected device | Non-clinical performance testing<br>Labeling |
| Malfunction of disinfected device due to material incompatibility with the high level disinfectant | Non-clinical performance testing<br>Labeling |
| Adverse tissue reaction in patient | Biocompatibility evaluation |

| | |
|---|---|
| Adverse respiratory, eye, or mucus membrane damage to end user due to error in high level disinfection processing | Human factors testing<br>Biocompatibility evaluation<br>Labeling |

In combination with the general controls of the FD&C Act, the foam or gel chemical sterilant/high level disinfectant 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 under challenging conditions:
   (i) Storage stability testing must demonstrate the real time stability and dynamics of the device formulation within the expiration date (shelf life) of the unopened product and within a use period of the opened container from the date of opening under the proposed storage conditions;
   (ii) Transport stability testing must demonstrate device resilience to transport conditions (such as temperature, pressure, and humidity), environmental factors (such as freeze and thaw), and mechanical impacts (such as the effect of drops on package integrity);
   (iii) Potency testing must demonstrate the sporicidal, mycobactericidal, fungicidal, bactericidal, and virucidal activities of the device;
   (iv) Simulated use testing must use the mycobacterium species most resistant to the germicide as the test organism on inoculated instruments to demonstrate a kill of at least $10^6$ inoculated mycobacteria under the labeled contact time;
   (v) In-use testing must test clinically-relevant microorganism on clinically used instruments, in accordance with the labeled contact conditions for high level disinfection, to confirm the results of simulated use testing;
   (vi) Testing must demonstrate compatibility with labeled devices and materials; and
   (vii) Chemical indicator validation must demonstrate a characteristic chemical reaction to the concentration of active ingredients of the germicide.
(2) The device must be demonstrated to be biocompatible.
(3) Human factors testing must demonstrate that the device can be used correctly, based solely on the device labeling.
(4) Labeling must include:
   (i) Directions for use, including:
      (A) Instructions for preparation and use of the germicide; cleaning steps in preparation for high level disinfection; high level disinfections of cleaned devices; rinsing, neutralizing, and removing residues, when needed; and reuse of the solution, if applicable; and
      (B) Chemical indicator for monitoring the Minimum Effective Concentration (MEC) or Minimum Recommended Concentration (MRC) of the product's active ingredient(s);
   (ii) Instructions for personal protective equipment to be used with the device;
   (iii) Instructions for disposal of the germicide and any neutralizers, including an instruction to check local and state regulations;
   (iv) Storage conditions and expiration date information for stock solution, opened containers, activated solution, and use-dilution;

(v) A statement that the end user should be trained in the reprocessing (decontamination and sterilization or disinfection) of medical devices and in the handling of toxic substances, such as liquid chemical germicides;
(vi) The germicide classification scheme;
(vii) General information on selection and use of germicides for medical device reprocessing;
(viii) Material and device compatibility and incompatibility information;
(ix) The microbial mode of action of germicidal activity;
(x) Precleaning agent/method compatibility and incompatibility; and
(xi) The toxicology profile of the final product formulation and information on adverse reactions following exposure to the product.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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 foam or gel chemical sterilant/high level disinfectant 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 Yongqing Chen at 240-402-9433.

Sincerely,

David Krause -S

for Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
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