



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 880

[Docket No. FDA-2026-N-6732]

### Medical Devices; General Hospital and Personal Use Devices; Classification of the Foam or Gel Chemical Sterilant/High Level Disinfectant

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the foam or gel chemical sterilant/high level disinfectant into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the foam or gel chemical sterilant/high level disinfectant. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on June 2, 2023.

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA (the Agency or we) has classified the foam or gel chemical sterilant/high level disinfectant into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe

this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the

device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

## II. De Novo Classification

On July 13, 2022, FDA received Tristel Solutions Limited's request for De Novo classification of the Tristel Duo ULT device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see

section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 2, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 880.6886.<sup>1</sup> We have named the generic type of device “foam or gel chemical sterilant/high level disinfectant,” and it is identified as 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.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Risks to Health and Mitigation Measures for Foam or Gel Chemical Sterilant/High Level Disinfectants

Identified Risks to Health	Mitigation Measures
Patient cross-contamination due to high level disinfectant lacking adequate potency on pathogens left on the surface of the disinfected device	Non-clinical performance testing; and Labeling
Malfunction of disinfected device due to material incompatibility with the high level disinfectant	Non-clinical performance testing; and 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; Biocompatibility evaluation; and Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in

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<sup>1</sup> FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for foam or gel chemical sterilant/high level disinfectants. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

### III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910-0485.

### **List of Subjects in 21 CFR Part 880**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

**PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES**

1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 880.6886 to subpart G to read as follows:

**§ 880.6886 Foam or gel chemical sterilant/high level disinfectant.**

(a) *Identification.* 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.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(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 or minimum recommended concentration 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.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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