DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Marcia Benedict
Director
Regulatory Affairs
Steris Corporation
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MAR 3 0 2012

Re: K100049
Verify Spore Test Strip for S40
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 880.6887
Regulation Name: Spore Test Strip
Regulatory Classification: Class II
Product Code: OVY
Dated: July 29, 2011
Received: August 1, 2011

Dear Ms. Benedict:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Verify Spore Test Strip for S40 an over-the-counter device under 21 CFR Subpart C that is indicated for assessing spore kill by the S40 sterilant at its use dilution in the System 1E Liquid Chemical Sterilant Processing System. A "no growth" result from the Verify Spore Test Strip for S40 after 24 hours of incubation indicates that the liquid chemical sterilization process achieved the conditions necessary to kill at least 1×10^5 viable spores (5 logs) on the test strip. The Verify Spore Test Strip for S40 does not confirm the expected full performance of the SYSTEM 1E Liquid Chemical Sterilization Cycle. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Verify Spore Test Strip for S40, and substantially equivalent devices of this generic type, into class II under the generic name, Spore Test Strip.

FDA identifies this generic type of device as: Spore Test Strip

> The spore test strip consists of a carrier or strip with a known number of spores, at least 5 $\log_{10}$ per strip, of known resistance to a particular liquid chemical sterilant in a liquid chemical sterilant processing system. A "no growth" result from the spore test strip after the specified pre-determined incubation period indicates that the liquid chemical

sterilization process achieved the conditions necessary to kill the specified minimum number of viable spores on the test strip which is 5 $\log_{10}$ spores/strip; it does not confirm the expected full performance of the liquid chemical sterilant processing cycle because full performance is a 6 $\log_{10}$ spore kill in a full liquid chemical sterilization cycle.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 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** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on July 7, 2011 automatically classifying the Verify Spore Test Strip for S40 in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On July 29, 2011, FDA filed your petition requesting classification of the Verify Spore Test Strip for S40 into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Verify Spore Test Strip for S40 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 petition, FDA has determined that the Verify Spore Test Strip for S40 indicated for assessing spore kill by the S40 Sterilant in the System 1E Liquid Chemical Sterilant Processing System 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.

Table - Potential Risks and Mitigations

Identified Potential Risk	Recommended Mitigation Measure
User handling error due to false fail Spore Test Strip device result due to technical malfunction	Spore Strip Characterization Simulated Use Testing Shelf Life Labeling
User handling error due to false pass Spore Test Strip device result due to technical malfunction	Spore Strip Characterization Simulated Use Testing Shelf Life Labeling
User handling error due to misunderstanding Spore Test Strip device use instructions	Labeling

In addition to the general controls of the FD&C Act, the Spore Test Strip is subject to the following special controls: (1) Spore Strip Characterization i.) Population of viable spores on strip shall be a minimum of 5 log10 after physical wash-off of spores from the strip by exposure to liquid chemical sterilant in the liquid chemical sterilant processing system, which should be validated over the claimed shelf life. ii.) The resistance characteristics of the viable spores on the strip should be defined and be validated over the claimed shelf life. iii.) The Spore Strip description should address the carrier material, how the spores are placed on the carrier, and whether there is any feature that minimizes spore wash-off. Bacteriostasis of the Spore Strip materials should be evaluated. iv.) Incubation time for viable spores on the strip should be validated under the specified incubation conditions over the claimed shelf life. (2) Simulated Use Testing: Simulated use testing should demonstrate performance of spore test strip in liquid chemical sterilant/high level disinfectant under worst case in use conditions over the claimed shelf life. (3) Labeling: Labeling should specify appropriate instructions, warnings, cautions, limitations, and information relating to viable spore population, resistance characteristics, and interpretation of a "no growth" result. 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 Spore Test Strip they intend to market prior to marketing the device and receive clearance to market from FDA.

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, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Elizabeth Claverie-Williams at (301) 796-6298.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
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