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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
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Central Region  
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May 15, 2008

**WARNING LETTER  
CIN-08-5964-15**

**VIA FEDERAL EXPRESS**

Walter M. Rosebrough  
President and Chief Executive Officer  
Steris Corporation  
5960 Heisley Road  
Mentor, Ohio 44060

Re: Steris System 1 Processor and Sterilant 20

Dear Mr. Rosebrough:

The Food and Drug Administration (FDA) has reviewed documents that were collected [REDACTED]. These records covered changes made to the Steris System 1 Processor (SS1), including the Sterilant 20, which is a liquid chemical sterilizer used to sterilize instruments such as endoscopes and bronchoscopes. The Steris System 1, including the Sterilant 20, is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

As explained below, our review of these documents and of agency records of premarket review decisions indicates that your device is adulterated under section 501(f)(1)(B) of the Act [21 U.S.C. 351(f)(1)(B)] because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency (21 U.S.C. 807.81(b)).

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Specifically, the device (Steris System 1 Processor and Sterilant 20) was cleared in 1989 for marketing under premarket notification (510(k)) submission number K875280. As discussed below, the documents collected [REDACTED] reveal that there have been significant changes or modifications in design, components, method of manufacture, or intended use, that require submission of a new premarket notification in accordance with 21 CFR 807.81(a)(3). Under that regulation, a new 510(k) must be submitted for a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. See 21 CFR 807.81(a)(3)(i). The changes described below are such significant changes. Therefore, until a 510(k) is submitted for the altered device and FDA issues a finding that this changed device is substantially equivalent to a legally marketed predicate, your device remains a class III device under section 513(f)(1) of the Act, 21 U.S.C. 360c(f)(1). Such devices are subject to the requirement of premarket approval under section 515(a) of the Act, 21 U.S.C. 360e(a).

Our investigation revealed the following changes that could significantly affect the safety or effectiveness of the device.

1. The cleared SS1's circulation pump was a [REDACTED] pump. In 1999, the pump was changed to a [REDACTED] pump. According to internal Steris documents, the original circulation pump failed for low flow performance and seal leakage that resulted in decreased SS1 reliability and consumer complaints. The change to a [REDACTED] pump altered the flow rate, the flow characteristics, and the flow through the lumen of the device. These changes significantly impact the function and delivery of the sterilant to and through an instrument.
2. The cleared SS1's high pressure pump was an [REDACTED] pressure pump with a flow rate of [REDACTED]. In 1992, you developed a new model SS1, Model 90. This new model had a high pressure pump with a flow rate of [REDACTED]. In 1995, as a result of consumer complaints of the Model 89 series high pressure pump leaking, your firm began installing pressure switches in the pumps to monitor the function of the high pressure pump. In 1998, your firm developed an "HP Pump Enhancement Kit," and in 1999, began replacing the [REDACTED] high pressure pumps in the Model 89A1 and 90B1 series with the new [REDACTED] high pressure pumps. The changes to the high pressure pump altered the flow rate and flow characteristics in the SS1 and through the lumen of the device. Therefore, these pump changes significantly impact the function and delivery of the sterilant to and through the device being processed.
3. In December 1996, your firm made changes to the original software used in the device as cleared in 1989, in response to reports that customers were receiving high pressure pump alarms due to low facility water pressure. In response, you changed the software program to limit the operation of the high pressure pump to the sterilant exposure phase and the final drain. Because of this software change, the high pressure pump no longer runs during the final rinse phase. This action may affect removal of chemical residues from the processed devices and may pose a risk to the patient.
4. On August 19, 2002, your firm sent correspondence to all of your customers stating that it had changed the connector design on the Quick Connect Kits from individual components to one unit, in which all of the components are tethered together. The design change was initiated following microbiological testing failures related to the older, individual-component connectors. Additionally, new connectors were developed to facilitate the adaptation of the flow unit to the

instrument to be processed. These changes to the connectors have a significant effect on the sterile fluid pathway and delivery of the sterilant.

5. The cleared SS1's chamber volume was [REDACTED]. After 510(k) clearance, your firm increased the chamber volume to [REDACTED] and then to [REDACTED]. Along with this large increase in the chamber volume, the Sterilant 20 formulation was altered, with the intent of maintaining the final peracetic acid (PAA) concentration given the larger chamber volume. This large increase in chamber volume, which apparently also prompted a change in sterilant formulation, could significantly affect the ability of the system to sterilize by altering how sterilant is delivered and the concentration of ingredients in the sterilant.
6. Following the clearance of the 510(k), your firm added five additional [REDACTED] ingredients ([REDACTED], [REDACTED], [REDACTED], and [REDACTED]) to the formulation of the Sterilant 20. This change to the sterilant formulation could significantly affect safety or effectiveness of the device, specifically, the effectiveness of the active ingredient and its ability to sterilize, and by altering the stability of the sterilant.

In addition to the changes above, each of which by itself would necessitate submission of a 510(k), the agency's review of the collected documents shows several additional changes to the SS1, including changes to the following: the sterile water filter housing; lid header block; material on the PV sleeves of the pinch valve; pressure relief added to the high pressure pump; the heater element changed from copper to stainless steel; and check valve on the drain block. These changes cumulatively result in a change in the overall device design that could significantly affect safety and effectiveness.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

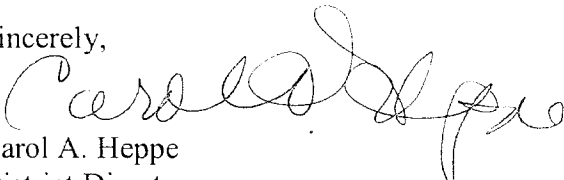
In addition, we request that your response address the following. Our review of the documents collected [REDACTED] revealed actions (detailed below) that you have taken on the SS1 that appear to meet the definition of a correction under 21 CFR 806.2.(d). In your response to this letter, we request that you indicate whether or not your firm considers these actions to be corrections or removals under that regulation, and if you do not consider them to be corrections or removals, to provide your rationale for that conclusion. If your firm does consider any of these actions to be corrections or removals, please provide a copy of your documented rationale as to why each such correction or removal is not required to be reported under 21 CFR 806.10, Reports of Correction and Removals. Please provide this information for the following:

1. On August 19, 2002, you sent communication to your customers introducing the new "tethered quick connect kits" with a new "Quick Connect Card" and "Laminated Wall Chart" labeling. The correspondence states for the customers to convert their inventory to the new quick connects, because they will reduce operator assembly time and the potential for operators connecting the incorrect scope to a specific quick connect.
2. On May 23, 2001, you initiated Engineering Change Order #010189 to provide field service with a kit for replacing the SS1's circulation pump impellers due to premature impeller failure (cracking) in the field. On February 1, 2003, you issued a Service Bulletin addressing the issue of the impeller prematurely cracking and allowing the black substance inside the impeller to be circulated through the system (SS1).
3. Engineering Report #ER-0003, dated May 31, 2000 and June 1, 2000, states that all the [REDACTED] high pressure pumps in the Model 89A1 and 90B1 SS1s have been replaced with the [REDACTED] high pressure pumps during the 1999 Pump upgrade program, which began in February of 1999. According to your "510(k) Modification Analysis Memo," and Service Bulletins 98030-1, 97019-1, 97054-1 and 98025-1, between April 1997 and March 1998, your firm made several changes to the high pressure pump assembly in an effort to address reported problems with the high pressure pump and high pressure pump switch and to reduce high replacement rates of these parts.
4. On August 6, 1999, you issued a service bulletin stating that all [REDACTED] circulation pumps in the SS1 were to be replaced domestically by the [REDACTED] pump, and internationally by the [REDACTED] pump. According to an interoffice memorandum, dated January 23, 1998, you switched to the new pumps because of poor reliability and a low circulation pressure condition.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may send a facsimile to her at (513) 679-2773, or email her at [gina.brackett@fda.hhs.gov](mailto:gina.brackett@fda.hhs.gov).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA.

Sincerely,

  
Carol A. Heppe  
District Director  
Cincinnati District