



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to Warning Letter SEA 02 - 03

Darwin D. McKibbin, President
Surgical Instruments Service and Savings, Inc.
723 Curtis Court
P.O. Box 2060
Sisters, Oregon 97759

WARNING LETTER

Dear Mr. McKibbin:

During an inspection of your establishment from May 22-25, 2001, Engineer Dennis Kawabata determined that your firm reprocesses medical devices including surgical instruments, compression sleeves, and other devices. These are defined as devices by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The recent inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows. The paragraphs are annotated with references to the items cited on the FDA-483. The inspectional findings were reviewed by the Center for Devices and Radiological Health (CDRH). You will find that some observations were not included on the FDA-483 which were found significant by CDRH to include in this letter.

1. Failure to validate a process with a high degree of assurance where the results of a process cannot be fully verified by subsequent inspection and test as required by 21 CFR 820.75(a).
 - a. Validation of the sterilization process failed to provide assurance that sterility is attained for all devices reprocessed at this site because there was no identification of the types of devices used for the sterilization validation. Therefore, there is no evidence that validation was performed with the most difficult to sterilize devices (item 1, FDA-483).

- b. The validation of the final wash failed to provide assurance of the effectiveness of the cleaning/disinfection process for all devices in that, (a) the study did not include the cleaning and [REDACTED] disinfection of the plastic enclosed area at the tip of the [REDACTED] trocar; and, (b) the study did not address the cleaning and [REDACTED] disinfection of electric cauterizing tips where the insulation has separated from the metal tip (item 2, FDA-483).
 - c. The validation of packaging process failed to provide assurance of the effectiveness of the sealing process in that the temperature setting was not identified (item 12, FDA-483).
 - d. There is no demonstration that moisture remaining inside the device after washing does not adversely affect bioburden levels or the effectiveness of the sterilization process. (CDRH).
2. Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met as required by 21 CFR 820.75(b). For example the cleaning process used reportedly included a [REDACTED] soak and [REDACTED] of ultrasound, even though procedure RAD 002.1 specifies a cleaning process with a [REDACTED] soak and [REDACTED] of ultrasound (item 18, FDA-483).
 3. Failure to maintain a device master record, which includes or refers to the location of device specifications as required by 21 CFR 820.181(a). For example, detailed device specifications have not been documented for all reprocessed devices (item 5, FDA-483).
 4. Failure to maintain a device master record which includes or refers to the location of production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications as required by 21 CFR 820.181(b). For example, for the final wash the ultrasound cleaning time specified on the Job Control Sheet differs from the time specified in the Washing Procedure (Test Report Sample #00-02767). This failure refers to item 19 on FDA-483.
 5. Failure to maintain a device master record which includes or refers to the location of quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used as required by 21 CFR 820.181(c). For example:
 - a. There are no established and approved acceptance criteria for incoming used devices (item 6, FDA-483)
 - b. Procedure 091100C, Washing and Packaging Department, is not adequate because: (a) the procedure does not identify the functions or operations to be checked for any type of device; (b) the procedure does not indicate what types of devices or which parts of any device are to be checked for size; and (c) the procedure does not document acceptance criteria for function or size. This failure refers to item 10 of the FDA-483.

- c. There are no established and approved acceptance criteria for final inspection of either specific or general types of instruments. This failure refers to item 7 of the FDA-483.
 - d. There are no documented acceptance criteria or specification for allowable levels of ethylene oxide and ethylene chlorohydrin following sterilization (CDRH).
 - e. There are no detailed acceptance criteria or procedures for testing seal integrity of packaging for all distributed devices to assure that packaging will maintain sterility of the devices. (CDRH)
 - f. Procedure 091100B, Refurbishing Department Checklist, does not list or refer to acceptance specifications or procedures for performing checks for electrical conductivity checks and function checks. This failure refers to item 9 of the FDA-483.
6. Failure to promptly remove all obsolete documents from all points of use or otherwise prevent unintended use of obsolete documents, as required by 21 CFR 820.40(a). For example, the following obsolete or suspended procedures were found in the Receiving Department workbook: (a) Procedure RAD 001.0, Receiving Incoming Devices, which had been superseded by RAD 001.1; and, (b) Procedure RAD 002.0, Device Cleaning and Distribution, which had been superseded by RAD 002.1. This failure refers to item 16 of the FDA-483.
7. Failure to make documents available at all locations for which they are designated, used, or otherwise necessary as required by 21 CFR 820.40(a). For example, a copy of Procedure 091100C, Washing and Packaging Department, is not in the Packaging Department book, even though some of the inspections listed in that procedure are performed in the Packaging Department. This failure refers to item 21 of the FDA-483.
8. Failure to establish and maintain procedures to control all documents including review and approval of changes to documents by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise; and to maintain change records including the approval date and when the change became effective as required by 21 CFR 820.40(b). For example the following records have no approval or effective date: (a) Procedures 091100A, 091100B, and 091100C; (b) Procedures RAD 001.1 and RAD 002.1; (c) the Washing procedure; (d) The Refurbishing procedure which also has handwritten changes on it; and, (e) the procedures for Receiving: Checking and Cleaning Items, which also has handwritten changes on it.
9. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria as required by 21 CFR 820.80(d). For example:
- a. There is no established and approved procedure for final release of a production lot following sterilization. This failure refers to item 8 of the FDA-483.

- b. Lots 3574 and 3575 (compression wraps) were released for shipment even though biological indicators were positive at the time of release and there is no documentation of resterilization. This failure refers to item 3 of the FDA-483.
 - c. Lot 3527 was released for shipment even though there is no record of biological indicator results in the sterilization logbook. This failure refers to item 4 of the FDA-483.
10. Failure to document acceptance activities as required by 21 CFR 820.80(e). For example, there is no documentation of the tests of water flow function for cauterizing tips (item 11, FDA-483).
11. Failure to implement and record changes in methods and procedures needed to correct and prevent identified quality problems as required in 21 CFR 820.100(a)(5). For example, there is no documentation of the implementation of corrective actions that were identified during the review of two complaints (item 13, FDA-483).
12. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record as required by 21 CFR 820.184. For example:
- a. There is no documentation to show performance of the wash procedure referred to in section 4.1.3 of QAP 13.0, Device Master Record. This failure refers to item 14 of the FDA-483.
 - b. Sterilization pre-conditioning times and temperatures are not recorded even though preconditioning specifications for time and temperature are established in the validation declaration sheet. This failure refers to item 15 of the FDA-483.
13. Failure to establish procedures for identifying training needs; to ensure that all personnel are trained to adequately perform their assigned responsibilities; and to document training as required by 21 CFR 820.25(b). For example, there is no documented training of any individual in the use of the following procedures: (a) Procedures 091100A, 091100B, and 091100C; (b) Procedures RAD 001.1 and RAD 002.1; (c) The Washing procedure; (d) the Refurbishing procedure; and, (e) the procedure for Receiving: Checking and Cleaning Items. This failure refers to items 17 and 20 of FDA-483.

Your correspondence dated August 30, 2001 providing your corrections to the inspectional findings has been received and reviewed. The following are comments based upon that review of your corrective efforts and they correspond numerically to the items listed on the FDA-483.

- 1. It appears that this analysis did not address the known contamination levels of the instruments and how they were cleaned/reprocessed. That is, in general terms, validation of these devices requires that the most difficult to clean/sterilize areas be inoculated first with a known level of bacteria and then cleaned in accordance with your established procedures.

Following the cleaning, the devices would be tested for the presence of microorganisms. If no bacteria survived, then the cleaning/sterilization process is considered validated.

2. This item remains open. You stated that the results from _____, _____, would be sent shortly after you received them. They have not been received.
9. This document does not provide the criteria which need to be checked or verified before final release of the sterilized finished devices.
13. The documents provided cover one of the two complaints listed on the FDA-483. Missing is the documentation for the complaint from _____, _____.
- 14-20. The corrections for these items appear acceptable and will be confirmed during the next inspection.

Remaining open are the corrections for items 5 through 7, 9 through 11, and 12.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to: seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Mr. Darwin D. McKibbin, President
Surgical Instruments Service and Savings, Inc., Sisters, Oregon
Warning Letter 02-03

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Your response should be sent to the U.S. Food and Drug Administration, 22201 23rd Drive SE,
Bothell, WA 98021-4421, Attention: Thomas S. Piekarski, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

Charles M. Breen
District Director