



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

M 2047 N

July 17, 1998

WARNING LETTER
CHI-31-98

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Raymond Dieter, Chairman of the Board
Masterile Reprocessing, Inc.
30W110 Butterfield Road
Warrenville, IL 60555

Dear Dr. Dieter:

During an inspection of your firm from May 20 to June 8, 1998, Inspector Patricia McIlroy determined that your firm performs reprocessing (including cleaning, resterilizing, and repackaging) of devices for local hospitals. The products that your firm reprocesses are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under Section 501(h) of the Act in that the methods used in or the facilities or controls used for the manufacturing, packing, storage or installation of devices are not in conformance with Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate critical manufacturing processes, as follows:

Failure to validate that cleaning processes are effective for their intended purposes. There have been no studies performed to ensure the effectiveness of cleaning or to show cleaning agent residues are not left on the devices.

Failure to validate the package sealing process.

Failure to validate that device functionality is maintained after reprocessing. While Mr. David Dieter stated during our inspection that the firm performs an evaluation of functionality for some devices, there is no procedure for this evaluation and it is not documented. Also, the evaluation is made before [REDACTED] processing. We are also concerned that cutting devices that are sharpened will perform as effectively as the original device. We do not believe that a final 100% visual inspection of the devices can assure that devices will perform as intended.

2. Failure to investigate a complaint of a device not meeting specifications. Masterile received a complaint from [REDACTED] for a blade lock malfunction for an Ethicon (Catalog 355LD) Trocar. Your evaluation of the device confirmed that during a "couple" of tests, "the lock did fail to keep the blade sheath locked when the blade lock was depressed". There was no attempt to determine the cause of the defect or determine whether additional reprocessing by Masterile may have contributed to the defect. Also, complaint reports do not include the date the complaint was received.
3. Failure to perform quality audits to ensure compliance with established quality system requirements and to determine the effectiveness of the quality system.

This letter is not intended as 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 (enclosed) issued to Mr. David Dieter at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge the response to our form FDA 483 by Mr. David Dieter, dated June 10, 1998. FDA's Center for Devices and Radiological Health has taken the position (detailed in a letter to medical device trade associations, dated December 27, 1995) that reprocessing of medical devices is considered manufacturing and is subject to the QSR. The letter states that "any person or firm that reprocesses medical devices for health care facilities and engages in repackaging, relabeling, or sterilization activities (including any associated process operations, e.g. cleaning) are required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal Regulations, 21 CFR Parts 820 and 801, respectively". Part 820 of 21 CFR is now entitled the Quality System Regulation for medical devices. Mr. David Dieter's response fails to address our concerns and provides no timeframe for implementation of correction.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, Federal agencies will be 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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 penalties.

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You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for conformance of your devices with the QSR and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

Please notify this office within 15 days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Mr. David Dieter, Operations Officer
Masterile Reprocessing, Inc.
30W110 Butterfield Road
Warrenville, IL 60555