

purged 8/15/97
HFI-35



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

File

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

August 14, 1997

WARNING LETTER

RETURN RECEIPT REQUESTED
VIA CERTIFIED MAIL

NWE-10-97

Robert W. Schaefer, President
Apple Medical Corporation
580 Main Street
Bolton, Massachusetts 01740

Dear Mr. Schaefer:

During an inspection of your establishment located in Bolton, Massachusetts, on July 15, 16, 18, and 23, 1997, our Investigator determined that your establishment manufactures various products, such as the 5 mm Hunt/Reich Secondary Cannula/Pyramidal Trocar. The 5 mm Hunt/Reich secondary cannula/pyramidal trocar is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is 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 (QSR)/Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish and maintain a quality system that is appropriate for the above listed device in that the Device Master Record (DMR) for the 5 mm Hunt/Reich

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Secondary Cannula/Pyramidal Trocar 5/Box, P/N 900-800, fails to contain the production process specifications and device specifications. For example the DMR on form FM-038018 Rev A, dated on 2/28/97, listed the MFG Procedure # as Not Applicable - Packaged at Contract Vendor; and listed the Special Processing Requirements as N/A. Further, the name of the contract vendor is missing.

2. Failure of the device history record (DHR) to demonstrate that this device is manufactured in accordance with the device master record, for example:
 - The Incoming Inspection Reports for the [REDACTED] dated April 29, 1996; the [REDACTED] dated June 19, 1996; and the [REDACTED] dated August 22, 1996, and March 22, 1997 were incomplete in that they did not list the dimension requirements or the quantities of components inspected, rejected, or final inspection results.
 - The DHRs for the [REDACTED], date issued June 4, 1996; and [REDACTED] dated issued August 19, 1996; were incomplete in that one or more of the following were not entered onto the forms: procedure #s, prepared by/date, approved by/date, document control no., revision, etc.
 - Reinspection records were not maintained for the 10 mm Cannula/Trocar Pyramidal w/5 mm Reducer, lot G6195.
3. Failure to follow your Processing of Product Complaints and Credit Returns, GP-019, Revision B, in that you failed to maintain a RGA (Return Goods Authorization) log and enter the following information into the RGA log: catalog number of the item, the item name, the name of the account requesting the RGA, the date of the RGA and the RGA number.
4. Failure to verify or where appropriate validate changes to a specification, method, process, or procedure before implementation. These activities shall be documented and approved. For example:
 - The [REDACTED] Inspection Report dated April 29, 1996, the OAL was changed from [REDACTED] per Tom. On an Inspection Report dated September 3, 1996, the OAL was changed to [REDACTED] Engineering change orders (ECO) or documentation to verify or validate these changes were not available.

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- The anodized process for the [REDACTED] was changed per fax dated June 26, 1996. An ECO or documentation to verify or validate this change was not available.
5. Failure to maintain purchasing controls to assure that products conform to specified requirements, for example, there are no records of acceptable suppliers.

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 FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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.

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 GMP deficiencies are reasonably related will be cleared 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 fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including 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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Apple Medical Corporation
580 Main Street
Bolton, Massachusetts 01740

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Your response should be sent to Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

John R. Marzilli
District Director
New England District Office

cc:

[REDACTED]