



November 9, 1998

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

WARNING LETTER
CHI-3-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard F. Jones, President
MediCor Corporation
236-B Egidi
Wheeling, IL 60090

Dear Mr. Jones:

During an inspection of your firm from September 14 to 15, 1998, Investigator Chad Schmeier determined your firm is a manufacturer of laparoscopic instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that your 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 the manufacture, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. In-process nonconformances and failures are not evaluated to determine the need for further investigation. The QSR requirements of 21 CFR, Part 820.90(a) state manufacturers shall establish procedures to control product that does not conform to specifications. The procedures shall address the evaluation of nonconforming product. The evaluation shall include a determination of the need for an investigation and notification to the persons or departments responsible for the nonconformance. The evaluation and any investigation shall be documented.
2. Device history records are not reviewed by a designated individual(s) prior to distribution of the devices. The QSR requirements of 21 CFR, Part 820.80(d) state finished devices shall not be released for distribution until:
 - a) the activities required by the device master record have been completed;

- b) the associated data and documentation have been reviewed;
 - c) the release is authorized by a designated individual(s); and
 - d) the authorization is documented by a date and the signature of a designated individual(s).
3. You failed to follow your established procedures for trending complaints and device failures. The QSR requirements of 21 CFR, Part 820.198(a) states manufacturers shall establish and maintain procedures for receiving, reviewing and evaluating complaints. Additionally, the term "Establish" is defined in 21 CFR Part 820.3(k) to mean, "... define, document (in writing or electronically), and implement."
- a) Procedure "QSP-14-02 Complaint Management System, Rev.0", requires monthly documentation of trends identified during the review of complaints; and
 - b) Procedure "QM - 01 Quality Manual, Rev. 2", requires periodic review of complaint and failure information for possible trends and the need for preventative action.

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 to you 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 receipt of Ms. Raquel Hanebuth's response to our Form FDA 483, dated October 2, 1998. We find the response adequately addresses our concerns. However, we require verification of correction either by FDA inspection or by third party auditor's written verification.

Until FDA has documentation to establish that all 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.

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Please notify this office in writing within 15 working days of receipt of this letter of your chosen method for verification of the corrections. Your response should be sent to Rachel Evans, Acting Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/
Raymond V. Mlecko
District Director