



March 13, 2000

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

**WARNING LETTER**  
**CHI-14-00**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Joachim D. Spiess, President  
Spiess Design, Inc.  
290 Telser Road  
Lake Zurich, IL 60047

Dear Mr. Spiess:

During the inspection of your firm from October 4 to 19, 1999, Investigator Chad Schmeier determined your firm manufactures endoscopes, bipolar forceps, and related accessories. 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. Failure to investigate complaints involving the possible failure of a device to meet any of its specifications or to maintain documentation of why no investigation was necessary. Failure to evaluate each complaint to determine if a Medical Device Report (MDR) is necessary.
2. Failure to maintain device history records for each batch, lot, or unit of medical device. There were no device history records for bipolar coagulation forceps bodies, hysteromats, and irrigation/aspiration pumps. The device history records for arthroscopes, sinusscopes, cystoscopes, laproscopes, and trocars did not contain acceptance records and lacked complete production records.
4. Failure to maintain a complete device master record for the bipolar coagulation forceps body and the irrigation/aspiration pump. The device master records for these devices did not include process specifications and quality assurance procedures.

5. Failure to appoint, and document the appointment of, a management representative with authority to establish and maintain the quality system. Our inspection determined the individual currently overseeing quality activities did not have the authority to ensure quality system requirements were maintained.
6. Failure of management with executive authority to periodically conduct management reviews to ensure that the quality system satisfies the requirements of the QSR and the manufacturer's established quality policy and objectives.
7. Failure to establish complete document control procedures. Our inspection determined that the firm's quality control manual stated that products are controlled "via an ECN system". However, the ECN system was not defined and there was no system in place to control documentation changes.
8. Failure to document the approval of procedures and specifications. For example, the following documents lacked an approval date and the signature of an individual responsible for approving the document:
  - Quality Control Manual
  - Bipolar Forceps Body Device Master Record (DMR)
  - Endoscope labeling
9. Failure to conduct quarterly quality audits as specified in the firm's quality control manual.
10. Failure to include, in service reports, the documentation of test and inspection data performed to assure the serviced device functions as intended.
11. Failure to establish acceptance procedures for the acceptance or rejection of incoming product. For example, your firm has not established acceptance/rejection criteria for incoming inspection of bipolar coagulation forceps inserts.
12. Failure to document periodic calibration of inspection, measuring, and test equipment. For example, Micrometer #599-1-32, used to ensure correct calibration of calipers, pin gages and other micrometers, has not been certified since August 21, 1996. The Quality Manual requires this instrument to be certified annually.

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.

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 requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

In order to facilitate FDA in making the determination that corrections to the deviations from the Quality System Regulation have been made and thereby, enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts for medical devices, and to resume Certificates to Foreign Governments for medical devices manufactured at your facility located in Peoria, IL, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment, located in Lake Zurich, IL, has initiated and completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections should be submitted to this office on the following dates:

- Initial certifications by consultant and establishment: September 15, 2000 (or sooner)
- Subsequent certifications of updated audits and corrections:
  1. August 15, 2001
  2. August 15, 2002

We acknowledge that you responded by letter, dated October 29, 1999, to our Investigator's FDA-483. We do not consider your response to the FDA 483 observations to be adequate because of the following:

FDA 483 #1a. Your response does not explain how your firm will document the following: who approves changes, why the change was made, or any verification/validation needed for the change. Also, your response does not indicate how the firm will assure the production personnel use the most updated drawings.

FDA 483 #1b. Your response identifies reworking non-conforming product as the firm's only corrective action and does not explain how the firm will attempt to prevent similar nonconformances from recurring.

FDA 483 #1c. Your response does not include any corrections to address this deficiency.

FDA 483 #2. Your response does not explain how the firm will assure relevant complaints are investigated. Your response fails to address training to assure complaints requiring an MDR will be properly identified and submitted to FDA.

- FDA 483 #4. Your response lacks documentation to assure the meeting was conducted. Your response admits that your firm lacks a person “versed in regulatory matters” and fails to provide any assurance that individuals responsible for conducting management reviews have the knowledge and experience necessary to determine if your firm’s quality system complies with the Quality System Regulation (QSR).
- FDA 483 #5b. Your response does not explain how your firm will assure complete production and quality assurance records will be maintained and fails to promise any corrections.
- FDA 483 #7. Your response does not contain any evidence that procedures have been established to control documents. Also your response does not explain how quality and manufacturing records and procedures will be controlled.
- FDA 483 #8. FDA performed two inspections after March 11, 1998, the date you stated in your response to the FDA 483, that the Quality Control Manual was “signed-off”. During the most recent inspection our investigator reported that you explained the Quality Control Manual was never reviewed by you or implemented by your firm. Your written response contradicts your statement during the inspection. Your response fails to provide assurance that the approved documents, identified in FDA 483 Observation #8, will be implemented.
- FDA 483 #10. Our investigator reported that, during the inspection, he explained that, your firm is responsible for devices that you repair under contract with another firm, and you must maintain records to assure repaired devices function as originally intended. Your response failed to promise any corrective action for this deficiency.
- FDA 483 #11. Your response does not include any corrective actions for this deficiency.

We ask that your response to this letter provide the details and specifics to demonstrate that necessary corrections will be made. Also, please provide an update regarding the progress of your firm’s corrective actions.

We request that you 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, 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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director