



September 21, 1998

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

WARNING LETTER
CHI-42-98

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 June 5 to 16, 1998, 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 maintain records of all complaints. For complaints in which the product is not returned, there is no record kept in the complaint file.
2. 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.
3. 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 and for electronic insufflators. The device history records for arthroscopes, sinusscopes, cystoscopes and laproscopes, did not contain acceptance records.
4. Failure to maintain a complete device master record for the bipolar coagulation forceps. The device master record does not include production and process specifications, quality assurance procedures and specifications, and packaging and labeling specifications.

5. Failure to control changes to devices to ensure that the changed device will perform as intended. A change to the PCB schematic for the electronic insufflator was made in October 1995. Also, a change was made to the low and high flow parameters. There was no documentation to ensure that these changes had been adequately reviewed. Also, there was no indication that these changes had been verified or validated to ensure their effectiveness.

The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you submitted a premarket notification submission [510(k)] before you began offering finished [REDACTED] for sale directly to hospitals and clinicians. This was confirmed during the inspection when the FDA investigator noted that your firm had not submitted such a premarket notification submission, and that you were marketing and distributing a finished device. Because you do not have a marketing clearance from FDA, your product is a violation of law. In legal terms, your product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

Furthermore, the [REDACTED] are misbranded under Section 502(b) of the Act in that the device is in package form and fails to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

The [REDACTED] are also misbranded under Section 502(f)(1) of the Act in that the labeling for the device fails to bear adequate directions for use and the device is not exempt from this requirement under 21 CFR 801.109 because there is no labeling on or within the package from which the device is to be dispensed which bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, or any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

The device is also misbranded under Section 502(e)(2) of the Act in that the package fails to bear a label that identifies the device by its common or usual name.

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.

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, 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 Rachel Evans, Acting Compliance Officer.

Sincerely,

\\s\
Raymond V. Mlecko
District Director