



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

May 14, 2003

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

Ref: 2003-DAL-WL-11

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. John E. Vendel  
Owner and President  
Southwest Instrument Company  
4815 South County Line Road  
Charleston, Arkansas 72933

Dear Mr. Vendel:

Our review of information collected during an inspection of your firm's operations at the office of your [REDACTED] Wilson Urology Associates, located at 2010 Chestnut Street, Suite A, Van Buren, Arkansas 72956, on April 8 through 9, 2003, revealed that your firm manufactures the Rosello Cavernotome Sets, Brook Cavernosal Dilator Sets, and Mohamed Closing Tools, which are surgical instruments that are intended for use during penile prosthesis implant surgeries. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, our investigator issued to you a list of significant CGMP inspectional observations which include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example, your firm has not established (a) a quality policy, a quality plan, device master records, device history records, and complaint files; and (b) procedures for quality and specification requirements that must be met by contractors, acceptance and rejection of finished devices, packaging and labeling activities, and complaint handling. See FDA-483 Items 1 through 9.

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2. Failure to establish and maintain the requirements, including the quality requirements, that must be met by suppliers, contractors, and consultants [21 CFR 820.50(a)] [FDA-483 Item 4]. Our inspection documented that your firm had no written device or raw material specifications for the contract manufacturing of the surgical instruments or that you did not know the grade of steel being used in the devices.
3. Failure to establish and maintain procedures for acceptance of incoming product [21 CFR 820.80(b)] [FDA-483 Item 5]. Our inspection also documented that the contractor wrapped the devices in newspaper and sent them to your firm for inspection. Your firm visually inspected the devices for defects but had not established any acceptance criteria or maintained records of device acceptance or rejection.
4. Failure to maintain the device master record for each type of device to include or refer to the location of device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications [21 CFR 820.181]. Our inspection documented that your firm had no device master records and that manufacturing activities had been conducted but not documented.
5. Failure to maintain and establish procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record [21 CFR 820.184] [FDA-483 Item 9].
6. Failure to maintain complaint files and failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)] [FDA-483 Items 7 and 8]. You verbally stated to our investigator that you had received some complaints of device defects, retrieved the defective devices, returned them to the contract manufacturer for repair, and then returned the repaired devices to the customers. There was no documentation of these activities.

Our inspection also documented that you had not registered your firm as a medical device manufacturer and listed the devices with the Food and Drug Administration (FDA) to ensure compliance with 21 CFR 807. Failure to register your firm and list your devices with FDA means your devices are misbranded under Section 502(o) of the Act. You can obtain the registration and listing form from our website at <http://www.fda.gov> for the filing of your firm's establishment registration and device listing.

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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 the regulations. The specific violations noted in this letter and in the FDA-483 issued at the close 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 violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Should you need general information about FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at <http://www.fda.gov> or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct 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 frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,

*Sylvia G. Yett*  
for Michael A. Chappell  
Dallas District Director

MAC:txt