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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

May 21, 2003

WARNING LETTER NYK 2003-26

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael A. McAndrews
President and Chief Executive Officer
Electro Surgical Instrument Company
37 Centennial Street
Rochester, New York 14611

Dear Mr. McAndrews:

During an inspection of your establishment located in Rochester, New York, conducted between April 4, 2003 and April 10, 2003, our investigator determined your establishment manufactures sigmoidoscopes. Sigmoidoscopes are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed these 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Management with executive responsibility has not ensured an adequate and effective quality system has been fully implemented and maintained at all levels of the organization. Specifically, management reviews have not been conducted. Manufacturing procedures have not been signed and dated by an authorized individual. There are no procedures for design changes, corrective and preventive action, medical device reporting, or personnel training. Quality audits are deficient. [21 CFR 820.20].

2. The quality policy and objectives are not established. [21 CFR 820.20(a)]

3. No management representative has been appointed to ensure quality system requirements are met, or to report to management on the performance of the quality system. [21 CFR 820.20(b)(3)]

4. Procedures for management review are not defined, documented, or implemented. [21 CFR 820.20(c)].

5. Management reviews are not conducted at defined intervals or with sufficient frequency. [21 CFR 820.20(c)]

6. Quality audits do not verify the quality system is effective in assuring regulatory requirements are being met. [21 CFR 820.22]

7. Individuals who perform quality audits have direct responsibility for those same areas which are being audited. [21 CFR 820.22]

8. Procedures for implementing corrective and preventive actions are not defined, documented, or implemented. [21 CFR 820.100(a)]

9. Procedures are not established or defined for the identification, documentation, and validation or verification of design changes prior to their implementation. [21 CFR 820.30(i)]

10. A formally designated unit has not been established to handle complaints. Furthermore, procedures have not been completed for receiving, reviewing, or evaluating complaints. [21 CFR 820.198(a)]

11. Formal Medical Device Reporting procedures have not been established. [21 CFR 803.17]

12. Some documents lack an approval date and signature of the designated, responsible individual. Examples include, "ESI Instrument Manufacturing", "Criteria for Manufacturing Operations", and "Final Inspection and Quality Control Instructions". [21 CFR 820.40(a)]

13. Document control procedures have not been established. [21 CFR 820.40]

14. The device master records fail to include or refer to the location of all quality assurance procedures. For example, procedures for in-process finishing, in-process leak testing, and the final shop QA for devices are not included. In addition, the procedure for assembly of light carriers is not documented. [21 CFR 820.181(c)]

15. Failure to establish procedures to identify training needs. Training is not documented. [21 CFR 820.25(b)]

16. There is no documentation of equipment identification. Calibration records lack the name of the individual performing each calibration and the date for the next calibration. [21 CFR 820.72(b)(2)]

17. Device history records lack the primary identification label and labeling for each device. [21 CFR 820.184(e)]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific

violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We are in receipt of your letter dated April 15, 2003 concerning your inspection. The letter fails to provide the Agency with specific details of the actions you intend to take. Furthermore, it is inadequate because you stated you will not reach full compliance for **six months**.

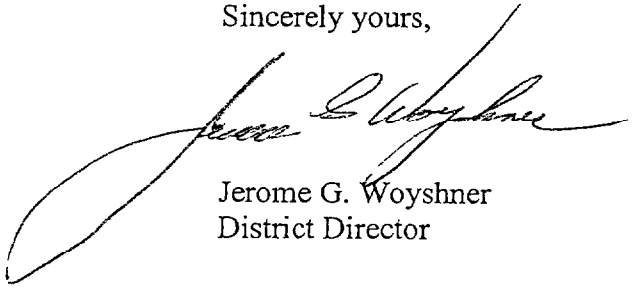
Federal agencies are advised of the issuance of all Warning Letters about devices so that they can take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved 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 within 15 working days of the receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to William J. Thompson, Compliance Officer, Food and Drug Administration, New York District, 300 Pearl Street, Buffalo, New York 14202.

Sincerely yours,



Jerome G. Woyshner
District Director