



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2936485

April 23, 1998

William R. Enquist, President
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

WARNING LETTER

Dear Mr. Enquist:

An inspection was conducted of your firm on February 17 through March 3, 1998, by U.S. Food and Drug Administration Investigator Francis J. Eng. The inspection found that your firm manufactures endoscopy equipment which are devices as defined by Section 201(h) of the Federal Food, drug and Cosmetic Act.

At the time of our inspection, the devices were found to be adulterated within the meaning of 501(h) of the Act, in that methods used in, or the facilities or controls used for manufacturing, packing, storage or installation were not in conformance with the Quality System Regulations (QSR) for Medical Devices as specified in Title 21 Code of Federal Regulations (CFR), Part 820, as follows: A lack of sufficient personnel with the necessary training and experience to assure all activities required by the Quality System Regulations are performed correctly; no documentation to substantiate complaints are being investigated and being brought to a satisfactory closure; during 1997, fifty-seven MDR complaints were filed with FDA beyond the thirty day limit; complaints requiring a failure investigation were not documented as being performed or the documentation was inadequate; the "order entry" system was found to be a secondary complaint system for which there was no written procedures, and for which failure investigations were not documented or were inadequately documented; there was no documentation of procedures for trending quality inspection records; and ESD guidelines were found to be inadequate in that

there was no information or specifications regarding standards, policies and equipment.

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 the FDA483 issued at the conclusion 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.

On March 23, 1998, we received a letter from Mr. Carlos Gonzalez, Vice President, which addresses each of the deficiencies revealed during our inspection. We acknowledge and appreciate the promptness of the response. Our review of the letter found that it illustrates adequate measures were immediately taken to correct the deficiencies and to preclude their recurrence. However, because of the nature of the deficiencies found during the inspection, the response letter from Mr. Gonzalez does not alleviate the necessity for the issuance of this warning letter.

If you have any additional information or comments regarding the inspection of your firm or this letter you should write to John M. Reves, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Patricia C. Ziobro".

Patricia C. Ziobro
District Director
San Francisco District