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Public Health Service

MAY 7 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Bruno Mattes  
Owner  
Tekno Medical Optik Chirurgie GmbH  
Sattlerstrasse 11  
D-78532 Tuttlingen, Germany

Dear Mr. Mattes:

During an inspection of your firm located in Tuttlingen, Germany on February 27, 1997, our investigator determined that your firm manufactures surgical instruments. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to hold finished devices in quarantine, or otherwise adequately control them until released, as required by 21 CFR 820.160. For example, it is unknown whether the following rejected instruments were reworked as required, or released for distribution without being reworked:
  - a. \_\_\_\_\_ of the devices were to be reworked because they did not meet finished device specifications.
  - b. \_\_\_\_\_ of the devices were to be reworked because they did not meet device specifications.
  - c. \_\_\_\_\_ all devices were to be reworked because they did not meet device specifications.
  - d. \_\_\_\_\_ of the devices were to be reworked because they did not meet device specifications.

- e. the devices were to be reworked because they did not meet device specifications. of
- f. the devices were to be reworked because they did not meet device specifications. of

2. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, there is no record indicating the quantity of devices released for distribution for the following:

- a. - NR. 8337-14TC,
- b. - NR. 9629-12TC,
- c. - NR. 9925-13TC,
- d. - NR. 8278-16TC,
- e. - NR. 8279-16TC,
- f. - NR. 8288-17TC,

3. Failure to establish, implement, and control reprocessing procedures to assure that the reprocessed device or component meets the original, or subsequently modified and approved specifications, as required by 21 CFR 820.115(a). For example, there are no reprocessing procedures.

4. Failure of the quality assurance program to consist of procedures adequate to assure the approval or rejection of finished devices, as required by 21 CFR 820.20(a)(2). For example, there are no procedures to assure that the quality assurance program approves or rejects all finished devices.

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 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 Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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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.

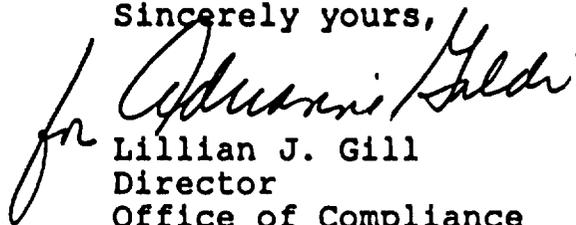
Given the serious nature of these violations of the Act, all devices manufactured by Tekno Medical Optik Chirurgie GmbH, Sattlerstrasse 11, D-78532 Tuttlingen, Germany may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing 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. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

  
Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health