



DEPARTMENT OF HEALTH & HUMAN SERVICES

g1983d  
New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Horst Becker  
Chief Executive Officer  
Heraeus Kulzer, Inc.  
99 Business Park Drive  
Armonk, NY 10504

November 19, 2001

Ref: NYK-2002-15

Dear Mr. Becker:

During an inspection of your device establishment located at the above address on October 1 through 22, 2001, our investigator determined that your firm imports and distributes Artglass dental restorative material, which is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is 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 regulation for medical devices, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820. The deficiencies included, but are not limited to, the following:

1. You failed to establish and maintain procedures for receiving, reviewing and evaluating complaints concerning Artglass material by a formally designated unit as required by 21 CFR 820.198. For example, during the inspection, we determined that Artglass complaints were handled in a manner different than complaints received for your other products. While there were written complaint-handling procedures for other products, there were no written complaint-handling procedures for your Artglass material.
2. You failed to analyze all sources of quality data concerning Artglass material to identify existing and potential causes of nonconforming product or other quality problems as required by 21 CFR 820.100. For example, your SOP for corrective and preventive action requires periodic analysis of quality reports to determine trends. There was no trending performed of Artglass complaints to detect recurring nonconformity problems.

3. You failed to maintain adequate device master records (DMR) that include packaging and labeling specifications, including methods and processes used as required by 21 CFR 820.181. For example, there were no written procedures for repackaging Artglass material and labeling into kits. During the inspection, we also determined that customers who had previously ordered Artglass kits are not always provided with inserts and labeling when reordering the Artglass kits.
4. You failed to document training to ensure that all personnel are trained to adequately perform their assigned responsibilities as required by 21 CFR 820.25. For example, there were no records documenting the training received by employees responsible for instructing dental laboratories on how to use the Artglass material.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations. The specific violations noted in this letter and in the Form FDA 483 (copy enclosed) issued to and discussed with you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm'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.

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. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved 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.

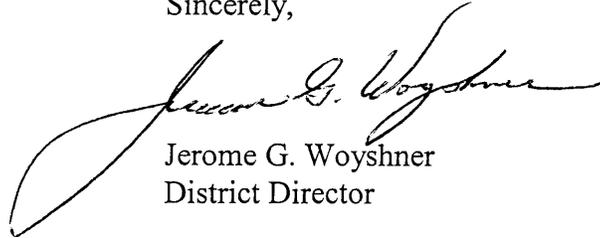
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office 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.

Heraeus Kulzer, Inc.  
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Your response should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Tel. (718) 340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner". The signature is fluid and cursive, with a large, sweeping initial "J" that extends to the left and underlines the rest of the name.

Jerome G. Woyshner  
District Director

Enclosure: Form FDA 483 dated October 22, 2001