



19701 Fairchild  
Irvine, California 92612-2506  
Telephone (949) 608-2900

**WARNING LETTER**

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

December 22, 2003

**W/L 16-04**

Mr. David Bailey  
President and CEO  
Staar Surgical Company  
1911 Walker Avenue  
Monrovia, California 91016

Dear Mr. Bailey:

During an inspection of your establishment located in Monrovia, California, on August 12 – September 4, 2003, our Investigators determined that your firm manufactures the Staar Surgical Implantable Contact Lens (ICL). ICL 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 under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to ensure that any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, as required by 21 CFR § 820.198(c). Specifically, your firm failed to perform root cause analysis of complaints involving diopter shift, blurred vision, cloudy vision, and posterior capsule tears.
2. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR § 820.80(b). Specifically, your firm's procedure for approving a vendor (test laboratory) does not assure that the methods used to test raw materials and finished devices have been validated.

The above-stated inspection also revealed that your device is misbranded under section 502(t)(2) of

the Act, in that your firm failed or refused to furnish material or information required by or under section 519 respecting the device. Specifically, your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR § 803.17(a)(1). For example, there were reports to your firm of serious injuries or malfunctions likely to cause or contribute to serious injuries attributed to the IOL/ICL, cartridges and injectors, and your firm failed to report these events to FDA. In one case, a physician had to perform a vitrectomy on a patient after the lens delivery system failed. In another incident, a physician had to suture a patient after the cartridge failed. Your company had knowledge of these serious injuries but failed to forward the information to the FDA. 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 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. 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 regulation 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 money penalties.

We received a response from [REDACTED], dated September 29, 2003, concerning the investigator's observations noted on the FDA 483. It appears that your firm's response to the MDR observations is inadequate. We believe that the information contained in your firm's record reasonably suggests that Staar Surgical Company received information that should have been reported to FDA as MDRs. In particular, we believe that complaints of lens tears, posterior capsule tears without vitrectomy, and cartridge and injector problems upon lens delivery should have been reported to FDA as MDRs pursuant to 21 CFR § 803.3(r).

The September 29<sup>th</sup> response to the GMP observations noted on the FDA 483 may be adequate. However, a follow-up inspection will be required to assure that corrections have been implemented. After the FDA re-inspection has taken place, and the implementation of your corrections has been verified, you will be notified whether your corrections are adequate.

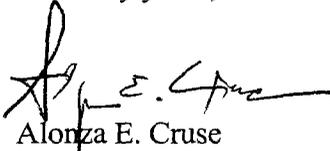
Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Your response should include both the

steps Staar Surgical is taking to rectify its MDR reporting procedures, as well as the steps the company is taking to report promptly all prior unreported events that fall within the reporting requirements of section 519 of the Act. 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. Your written response should be sent to:

Director of Compliance  
U.S. Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, California 92612

If you have any questions regarding this letter, please contact Ms. MaryLynn Datoc, Compliance Officer, at (949)608-4428.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is stylized with a large initial "A" and a long horizontal stroke.

Alonza E. Cruse  
District Director  
Los Angeles District Office