



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

93951d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

April 14, 2003

Ronald Philip  
President  
Vision Chips, Inc.  
P.O. Box 2855  
Laguna Hills, CA 92654

W/L: 30-03

Dear Mr. Philip:

During an inspection of your firm located in Aliso Viejo, California, from March 4 to 5, 2003, our investigator determined that your firm manufactures OB/GYN ultrasound information and reporting systems with integrated image archiving systems. These systems are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that the 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, their manufacturing, packing, storage, and installation are not in conformance with current Good Manufacturing Practice (GMP) requirements, as specified in the Quality System Regulation, Title 21 Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain a quality system that is appropriate for specific devices manufactured [21 CFR 820.5 and 21 CFR 820.20]. For example,
  - Management with executive responsibility has not ensured that the quality system requirements are effectively established and maintained.
  - Management with executive responsibility has not established a quality policy and objectives for, and commitment to, quality for specific devices manufactured.
  - No quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured has been established or implemented.
  - No quality system procedures and instructions have been established and implemented.

Vision Chips, Inc.

- No procedures for management reviews have been established or implemented to ensure that the quality system satisfies the requirements of the Quality System Regulation and the quality policy and objectives of the firm.
  - No management representative has been appointed for ensuring that the quality system requirements are effectively established and maintained, and for reporting on the performance of the quality system to management for review.
2. Failure to establish procedures for conducting quality audits, and failure to conduct any audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].
  3. Failure to establish and implement procedures to control the design process of the specific devices manufactured by your company [21 CFR 820.30]. For example,
    - No design and development plans have been established or implemented.
    - Procedures for planning and conducting reviews of the design results at appropriate stages of a device's design development have not been defined.
    - Procedures for validating the design of devices have not been defined.
  4. Procedures for corrective and preventive actions fail to include requirements for verifying or validating the action to ensure that such action is effective and does not adversely affect the finished devices [21 CFR 820.100(a)(4)]. Specifically, there are no procedures to address the need and circumstances where verification or validation is required after performing a corrective and preventive action.
  5. Failure to establish and implement installation and inspection instructions and test procedures for your OB/GYN ultrasound information and reporting and the image archiving systems, to ensure that the devices will perform as intended after installation [21 CFR 820.170].

We acknowledge that you have submitted a written response to this office dated March 19, 2003, concerning our investigator's observations noted on the form FDA 483 issued and discussed with you at the conclusion of the inspection. We have reviewed your response and while your letter promises corrections to the observations listed on the form FDA 483, we must consider the response as inadequate because no evidence or documentation of corrections was provided with your response. In regards to your request for assistance, FDA cannot assist your company in making the corrective actions. Furthermore, FDA cannot recommend or endorse a particular consultant. We can offer some guidance and information about requirements that may be useful. You may obtain general information about FDA's requirements for manufacturers of medical devices by contacting FDA's Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

Vision Chips, Inc.

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 conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA as well as any others that may exist. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions for those systems.

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 pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability 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.

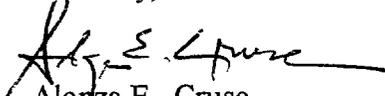
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar 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.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Acting Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse  
District Director  
Los Angeles District Office