



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard E. Feinbloom, President
Designs for Vision, Inc.
760 Koehler Avenue
Ronkonkoma, NY 11779

April 9, 2003

Ref: NYK-2003-21

Dear Mr. Feinbloom:

During an inspection of your establishment located at the above address on March 24 through 28, 2003, our investigator determined that your firm manufactures the "DayLite XeNon Light Source," which is used with a fiber optic cable and headset to provide illumination during surgery and other procedures. This product 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 and the medical device reporting requirements of 21 CFR Part 803. The deficiencies include, but are not limited to, the following:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a). We have received your firm's written responses dated April 1 and 2, 2003. However, the responses do not adequately address this deficiency. For example, the new complaint handling procedure you submitted does not include the date and signature of the individual(s) approving the document as required by 21 CFR 820.40.
2. Failure to develop, maintain, and implement written medical device reporting (MDR) procedures as required by 21 CFR 803.17 and, which supplements the provisions of 21 CFR 820.198(d).
3. Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22.

4. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality as required by 21 CFR 820.20(a).
5. Failure to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90(a). For example, there were finished device inspection reports documenting nonconforming light outputs from the DayLite XeNon Light Source. However, the inspection reports did not document any evaluation performed, investigation initiated, results of any investigation, or any corrective actions taken.
6. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers as required by 21 CFR 820.50(a). For example, there were no documented evaluations of the suppliers of the xenon bulbs and power supplies used in the DayLite XeNon Light Source to determine their ability to meet specified requirements.
7. Failure to establish and maintain procedures for finished device acceptance to ensure that each finished device meets acceptance criteria as required by 21 CFR 820.80(d). For example, there were several instances where the DayLite XeNon Light Source was released for distribution even though the lamp output test failed to meet its minimum specification. Further, there were several instances where finished device inspection forms were missing.
8. Failure to review and approve changes to documents as required by 21 CFR 820.40(b). For example, engineering release/change notices for the DayLite XeNon Light Source did not include identification of the affected documents, the signatures of the approving individuals, the approval dates, and when the changes became effective.
9. Failure to document personnel training as required by 21 CFR 820.25(b). For example, there was no documentation of employees trained by engineering in the assembly and testing of the DayLite XeNon Light Source.
10. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated as required by 21 CFR 820.72(a). For example, the light meter equipment used for final acceptance testing of the light intensity of the DayLite XeNon Light Source was last calibrated on January 31, 2001

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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 Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive action on your Quality System.

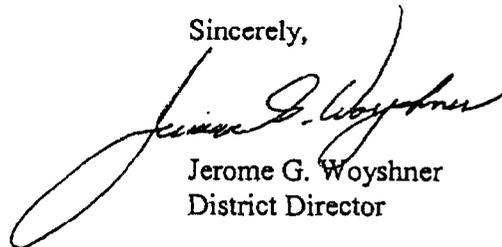
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies 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 FDA 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.

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,



Jerome G. Woyshner
District Director

Enclosure: Form FDA 483 dated March 28, 2003