



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445
Telephone (949) 798-7600

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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

September 24, 1998

WL-45-8

Dr. Colette Cozean
President/CEO
Premier Laser Systems, Inc.
3 Morgan
Irvine, CA 92618

Dear Dr. Cozean:

During an inspection of your firm conducted between June 26 to July 14, 1998, our investigators determined that your firm manufactures medical lasers, fiber optic delivery systems, and associated products for a variety of dental, ophthalmic, and surgical applications. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation as prescribed by Title 21, Code of Federal Regulations, (CFR) Part 820, as follows:

1. Failure to maintain records of investigations of all complaints involving the possible failure of a device and/or records describing the reason no investigation was made. [21 CFR 820.198(b)] For example, our investigation disclosed that your firm had no written documentation describing the rationale for not performing investigations or documenting the results of investigations of several reported complaints, specifically complaints received on your devices during the Centauri Fiber Delivery Systems [REDACTED], and Centauri Fiber Delivery Systems telephone complaints received by your firm.

2. Your laser system is adulterated within the meaning of section 501(f)(1)(B) of the Act, in that a video which is used for training users of your device promotes the use of the device for the removal of composite material. Your laser is a Class III device which under section 515(a) is required to have in effect an approved application for premarket approval. Your laser is not exempt from section 515 under section 520(g) because there is no approval exemption for investigational use regarding the removal of composite material. In addition, use of your laser system for this indication has not been found to be substantially equivalent through the premarket notification (section 510(k)) process. This use causes the device to be misbranded within the meaning of section 502(o) of the Act, in that notices or information respecting use of the device for this indication were not provided to the FDA as required by section 510(k).

3. In addition, your laser system is further misbranded under section 502(t)(2) because of failure to furnish information required under the MDR regulations. CFR 21, 803.50(a) requires that firms report within 30 days, whenever the manufacturer becomes aware of information from any source, that reasonably suggests that a device marketed by the manufacturer: (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned and as such device or similar marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur. Any source including telephone complaints and customer surveys conducted by your firm, disposable and/or single use devices are not exempted from MDR reporting.

Manufacturers are responsible under 21 CFR 803.50(b)(2) for conducting an investigation of each adverse event and evaluating the cause of the event. Investigations of complaints that appear to involve MDR reportable events (death, serious injuries, or malfunctions) are required. If a manufacturer is unable to provide complete information in their documentation for the MDR report, it must provide a statement explaining why such information was incomplete and what steps were taken to obtain such information.

Under 21 CFR 803.18(b)(1), MDR event files must document their investigations of MDR related events and maintain this document in their MDR event files. This includes all documentation of the entity's deliberations and decision making processes used to determine if a device related death, serious injury, or malfunction was or not reportable under MDR regulation.

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 violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office two responses concerning our investigators' observations noted on the form FDA-483. It appears that the responses are adequate where it addresses those observations relating to the manufacturing of the device covered by 510(K), but further verification will be necessary during our reinspection.

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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates to Foreign Governments for Export 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, injunctions, 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 reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,



Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Administration
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320