

M3169N



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 19 1999

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Philip W. Passy
President
Laser Systems International, Inc.
467 Yacht Club Road
Hartwell, Georgia 30643

Dear Mr. Passy:

This letter is written to advise you of noncompliances with the Federal laser product performance standard encountered during review of the report on the Aculaser Laser Therapy device, dated March 1, 1999, Accession Number 9910360.

1. 21 CFR 1040.10(f)(3). The Aculaser lacks a remote interlock connector, required for all Class IIIb and IV laser systems.
2. 21 CFR 1040.10(f)(4). The Aculaser lacks a key control that, when removed, renders the laser system inoperable. According to the report, the key on the Aculaser console is removable in the 'On' position leaving the laser system still operable.
3. 21 CFR 1040.10(f)(5)(ii). The Aculaser lacks an adequate emission delay signal, an indication sufficiently prior to laser emission to allow appropriate action to be taken to avoid exposure.
4. 21 CFR 1040.10(f)(6). The Aculaser lacks a beam attenuator.
5. 21 CFR 1010.3. The Aculaser lacks an identification label including the date of manufacture.
6. 21 CFR 1040.10(g)(6). The Aculaser lacks noninterlocked protective housing labels on the probes.

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7. 21 CFR 1040.10(h)(1)(iii). The Aculaser Operation manual lacks label reproductions and an indication of their locations on the product.
8. 21 CFR 1040.10(h)(1)(iv). The Aculaser Operation manual lacks the "Caution - use of controls or adjustments..." warning statement.
9. 21 CFR 1010.2. The laser product report, Part 8, lacks samples of documents that describe, specify, or relate to quality control testing and procedures used to ensure compliance of the Aculaser to the standard.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or from failure to submit required reports. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions. 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.

You should take prompt action to correct these deficiencies. Failure to promptly correct these deficiencies may result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to, injunction and/or imposition of civil penalties as provided for in section 539.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product

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distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

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With regard to medical claims and promotion on your website, in the U.S. any medical device must have premarket approval or premarket clearance from the Food and Drug Administration (FDA) prior to marketing for any claimed human indication. To date, the FDA has approved no biostimulation laser therapy devices for humans; therefore, it is illegal for any claims of clinical effectiveness to be made. Our office has issued notifications and warnings to firms suspected of illegally marketing these devices with claims of effectiveness.

Your response should be sent to: General Surgery Devices Branch, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. Please send a copy of your response to: Compliance Branch (HFR-SE140), Food and Drug Administration, 60 Eighth St. N.E., Atlanta, Georgia 30309. If you have further questions on these requirements, please contact Cory Tylka of the General Surgery Devices Branch at (301) 594-4595.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Handwritten:
4/19/99