



H&I-35 (urgency) 11/2/97

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850**WARNING LETTER**

Sent via facsimile and Federal Express

Robert L. Epstein, M.D.
The Center for Corrective Eye Surgery
5400 W. Elm Street
McHenry, Illinois 60050

Dear Dr. Epstein:

The Food and Drug Administration (FDA) inspected your medical practice on September 3, 4 and 15, 1997, and determined that you are using an unapproved excimer laser system assembled by [REDACTED] an engineering consultant with [REDACTED] and representatives of [REDACTED].

This laser system contains software developed by [REDACTED] with your input into its design. This excimer laser system is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). Excimer laser systems are Class III devices which are required to have in effect an approved application for premarket approval (PMA) or an approved Investigational Device Exemption (IDE).

Medical devices used by physicians in the course of their practice to treat patients are "marketed" and "held for sale" within the meaning of the Act, and thus, are subject to the provisions of the Act. Your excimer laser system is adulterated under section 501(f)(1)(B) of the Act because it is a Class III device under section 513(f), which is required to have in effect an approved application for PMA or an approved IDE, and no such PMA or IDE is in effect for your excimer laser. Further, your continued use of this device to treat patients is also a violation of the Act.

In addition, your excimer laser system must comply with the requirements of the Federal Performance Standards for lasers which are found in Title 21 of the Code of Federal Regulations, (CFR) parts 1040.10 and 1040.11.

Section 538(a) of 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 standards. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. To date, we have not received a Laser Product Report from [REDACTED] for this excimer laser system as required under CFR 1002.10.

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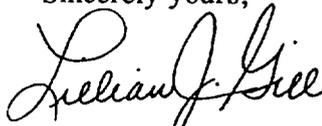
Please note that FDA does not consider your excimer laser to be a custom device. Section 520(b) of the Act establishes five conditions, each of which must be met for a device to be a custom device. The Act's custom device definition requires, in part, that the device be made to meet either the specific anatomical requirements of an individual patient or the special needs of an individual practitioner; a practitioner's special needs may be either an individual anatomical need or a special practice need that is not shared by other physicians.

We do not believe your device is designed to meet any special anatomical needs that you or an individual patient of yours may have. In addition, we do not believe the requirements of your medical practice are unique because they are shared by numerous other health professionals. Accordingly, your laser is not a custom device and is not exempt from the requirement under the Act that this device must have an approved PMA or IDE in effect.

Please notify this office within 15 working days of your receipt of this letter as to what, if any, actions you are taking, or plan to take, to bring your device into compliance with the Act. Your response should also clearly state whether or not you have ceased using the device to treat patients. Failure to immediately and completely cease clinical use of the device upon receipt of this letter and failure to bring your device into compliance with the Act, may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Please note that no extensions of the 15 day response period will be given.

Your response should be sent to the attention of Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch (HFZ-331) at the letterhead address. In addition, please send a copy of your response to Mr. Stephen D. Eich, Compliance Officer, U.S. Food and Drug Administration, 300 S. Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606. If you have further questions, please contact Mary-Lou Davis at (301) 594-4613 extension 127 or FAX: (301) 594-4638.

Sincerely yours,



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