



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 30 1997

WARNING LETTER

Jerry W. Maida, M.D.
580 West Eighth Street
Suite 9017
Jacksonville, Florida 32209

Ref:OC:14-1356

Dear Dr. Maida:

On January 21, 1997, you submitted an application for an Investigational Device Exemption (IDE) for your excimer laser system for use in refractive eye surgery. On February 19, 1997, the FDA's Office of Device Evaluation (ODE) sent you a letter disapproving your IDE application, citing deficiencies in the application.

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 Federal Food, Drug and Cosmetic Act (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 it. 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. We acknowledge receipt of a Laser Product Report from you for this excimer laser system. Due to the fact that the report was submitted as part of your IDE application, rather than to the Office of Compliance, the report was not logged in until May 12, 1997. Unfortunately, significant portions of the report are missing; therefore, it is impossible to determine the full extent of the noncompliances at this time. The following noncompliances were observed:

1. 21 CFR 1040.10(g)(5). The aperture label is not located in close proximity to the actual output aperture, as required by this section.

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2. 21 CFR 1040.10(g)(6)(v) and (7)(v). The noninterlocked and defeatably interlocked protective housing labels lack the correct wording for a Class IV laser product.
3. 21 CFR 1040.10(g)(8)(ii). The warning logotype label and protective housing labels lack the phrase "visible and/or invisible" preceding "laser radiation."

All sections of the report after Part 7.2 appear to be missing; i.e., the remainder of Part 7, Part 8, Part 9 and Part 10. Furthermore, there is no Operation Manual to demonstrate compliance with 21 CFR 1040.10(h)(1) and 1040.11(a)(2). Copies of the certification label, identification label, and aperture label are missing. Lastly, there is no indication of quality assurance during manufacturing and no records of testing and inspection to assure compliance with the performance standard. Please submit all missing sections, operation instructions, and quality assurance material to demonstrate compliance with these requirements.

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. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

Although your excimer laser was purportedly manufactured, in part, based upon your specifications, FDA does not consider it to be a custom device. Section 520(b) of the Act establishes five conditions, each of which must be met by a device to be a custom device. The Act's custom device definition requires 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 the requirements of your medical practice are unique because they are shared by numerous other health professionals. In addition, we do not believe your device is designed to meet any special anatomical needs that you or an individual patient of yours may have. 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.

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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. Timothy J. Couzins, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809. 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