



FOOD AND DRUG ADMINISTRATION

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Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
Program Enforcement Branch II
2098 Galther Rd
Rockville, MD 20850
(301) 594-4723

WARNING LETTER

June 11, 1997

Mark Kislinger, M.D. Ph.D.
Vision Correction Center of Pasadena
709 E. Colorado Blvd., Suite 101
Pasadena, California 91101

IDE: G960213

Dear Dr. Kislinger:

The purpose of this letter is to bring to your attention regulatory issues that were raised as a result of the Food and Drug Administration's (FDA) April 1997 inspection of your excimer laser system located at your Pasadena site. Your system does not meet the necessary requirements for treating patients. It is not the subject of an approved premarket approval application (PMA), nor does it meet the definition of a custom device. Among other conditions, a custom device must be intended for use by an individual patient and must be made specifically for that patient, or must be intended to meet the special needs of an individual practitioner. These special needs may be either an individual anatomical need or a special practice need that is not shared by other physicians. Your laser system meets neither of these conditions, therefore, you must have an approved Investigational Device Exemption (IDE). Under an IDE, you would be limited to treating a specified number of patients/subjects using specific procedures to collect data to demonstrate that your laser is safe and effective.

Although you have an approved IDE, FDA believes that you have violated the conditions of this approval and the IDE regulations under which you were allowed to use your laser to collect data to demonstrate the safety and effectiveness of your laser. These failures to adhere to the conditions of approval and to follow the IDE regulations include:

1. You have failed to provide in 45 days all of the information requested by our Office of Device Evaluation in its February 14, 1997 letter conditionally approving your IDE.
2. You have treated patients without the approval of an Institutional Review Board (IRB) (and therefore without submitting certification of IRB approval to FDA), which are violations of the IDE regulations. (See, for example, Title 21 of the Code of Federal Regulations, sections 812.40, 812.42, 812.62, and 812.110.)
3. You have refused to allow FDA inspectors to look at your records related to this IDE which you are required to maintain (under Title 21 of the Code of Federal Regulations, section 812.40), and which FDA may inspect, copy and verify (pursuant to Title 21 of the U.S. Code, section 374 part e, and Title 21 of the Code of the Federal Regulations, section 812.145).

Furthermore, although you have refused to provide FDA with the full information necessary to determine how many patients you have treated, the agency believes that you have treated more than the 20 patients/subjects specified in the conditional approval of your IDE.

You may not use your laser beyond the conditions of approval of your IDE. Therefore, you must immediately stop clinical use of your excimer laser upon receipt of this letter. You must also notify FDA of how you plan to bring your device into compliance with IDE regulations and the conditions of approval of your IDE. Failure to do so may result in FDA taking regulatory action against you without further notice. These actions may include, but are not limited to, proposing to withdraw approval of the IDE application, seizure, injunction, and/or civil penalties.

Within 15 working days of your receipt of this letter, please notify this office what actions you are taking or plan to take to bring your device into compliance with the requirements of the Act. Your response should state clearly whether you have stopped using the device to treat patients, and whether you will treat any additional patients before you receive FDA approval of your revised IDE.

You should send your response to this letter to the attention of Thomas C. Knott, Division of Bioresearch Monitoring (HFZ-312) at the address in the letterhead. In addition, please send a copy of your response to Mr. Dannie E. Rowland, Compliance Officer, Food and Drug Administration, 19900 MacArthur Blvd. #300, Irvine, California 92612.

Your response should also include a supplement to your Laser Product Report, Accession Number 9710602, describing the modifications made to your laser, as you stated during the April 23, 1997, inspection. Include copies of revised labels and the revised Operation Manual to demonstrate compliance with the Federal Performance Standards for Lasers (Title 21 of the Code of Federal Regulations parts 1040.10 and 1040.11).

Sincerely yours,



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