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HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 30 1997

WARNING LETTER

Philip C. Roholt, M.D.
4425 Metro Circle NW
North Canton, Ohio 44720

Dear Dr. Roholt:

You were identified as an investigational site in an October 22, 1996, application for an Investigational Device Exemption (IDE) submitted by Dr. Mark Kislinger. On November 21, 1996, the FDA's Office of Device Evaluation (ODE) sent Dr. Kislinger a letter disapproving this IDE application, citing deficiencies in the application. On January 8, 1997, Dr. Kislinger submitted an amendment to this IDE application which answered some of the deficiencies in the original application. On February 14, 1997, ODE granted conditional approval to Dr. Kislinger only. Approval was not granted for your investigational site.

On February 19-20, 1997, the Food and Drug Administration (FDA) inspected the former site of your medical practice in Green, Ohio and on May 13, 1997, we inspected your current location in North Canton, Ohio. These inspections revealed that you are continuing to use an unapproved excimer laser system, which was manufactured by Photon Data, Inc., Winter Park, Florida, and assembled by yourself and Mr. Chung Lee, consultant with Nexus Technology, Inc., Oviedo, Florida. Your excimer laser is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

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 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 record keeping requirements and the requirements of the Federal performance standard for lasers which are found in Title 21 of the Code of Federal Regulations, (CFR) parts 1002, 1040.10 and 1040.11. We acknowledge receipt of a Laser Product Report dated April 9, 1997, from you for this excimer laser system. The following noncompliances were observed during review of the report:

1. 21 CFR 1040.11(a)(2). The Operation manual lacks calibration procedures for the laser's internal measurement system and a schedule for calibration. Although we would not object to your inclusion of a statement to the effect that only authorized service personnel may perform the procedure, the requirement is clear that the instructions must be supplied to the user.

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."

4. 21 CFR 1040.10(h)(1)(iii). The Operation manual lacks reproductions of the warning labels required by the laser product performance standards.

5. 21 CFR 1002.30(a)(2). There is no record of final testing and inspection of the performance features and labeling required by the performance standards to assure compliance with the standards.

In addition, copies of your certification, identification, and aperture labels were not included in the report. Please submit copies of all revised labels, revised operation instructions, and quality assurance material to demonstrate compliance.

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 standard. This section also states that it is unlawful for any manufacturer to fail to establish and maintain required records or to submit required reports. Failure to respond to these noncompliances may be considered to be a 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.

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. Lawrence E. Boyd, Compliance Officer at the Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, telephone (513) 684-3501, extension 167. If you have further questions, please contact Ms. Mary-Lou Davis at (301) 594-4613 extension 127 or FAX: (301) 594-4638.

Sincerely yours,

Lillian J. Gill

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