



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER
VIA EXPRESS MAILFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JUL 26 2001

Dr. Farzad Yaghouti, M.D.
Global Laser Vision
6950 Friars Road, Suite 100
San Diego, California 92108

Dear Dr. Yaghouti:

During an inspection of your medical facility in Huntington Beach, California on May 17 and 30, 2001, our investigator determined that you are using an excimer laser system for refractive surgery. You indicated that Nidek Co., Ltd. in Japan manufactured this laser (serial number [REDACTED] in February 1997, prior to the approval of their premarket approval application (PMA) for the EC-5000 excimer laser. You indicated that this laser was purchased from Nidek Medical Pty., Ltd. (Australia). [REDACTED] arranged this purchase. A copy of a letter referencing the purchase of a refurbished Nidek EC-5000 excimer laser (serial number [REDACTED] dated December 6, 2000, was provided to our investigator. Please explain the discrepancy with the serial number. We are aware that you have a second Nidek laser at your San Diego office that was obtained through Nidek, Inc. in the U.S.A.

You also provided a copy of an October 6, 2000, letter from Mr. John Byrne from Nidek Medical Pty., Ltd. to Mary-Lou Davis/FDA that stated Nidek Medical Pty. Ltd.'s intention to modify EC-5000 products to meet the U.S. PMA requirements and to certify those modifications. FDA has no record of ever receiving this letter. You also provided a copy of a letter Nidek Medical Pty. Ltd. sent to recruit potential customers of refurbished Nidek lasers dated October 6, 2000. Nidek Medical Pty. Ltd. appears to have no authority to refurbish these lasers.

Nidek Inc.'s attorney, Ms. Kathryn Gleason, Esq., has advised FDA that Nidek, Japan and the U.S. Nidek firms do not wish to remanufacture gray market Nidek lasers to bring them into compliance with the specifications of Nidek's PMA approval. Nidek, Japan has also not authorized any other firm to re-manufacture these devices to bring them into compliance with the specifications of their PMA. We also consulted with Nidek's attorney regarding your serial number [REDACTED] and were advised that Nidek, Japan never received this unit from Nidek Medical Pty. Ltd., Australia for re-manufacturing or any type of refurbishment.

Your modified Nidek also needs to be certified as in compliance with the Federal laser product performance standard pursuant to 21 Code of Federal Regulations (CFR) 1040.10(i). Laser products manufactured after August 1, 1976, are subject to all the applicable requirements of the Federal performance standard for laser products specified in 21 CFR 1040.10 and 1040.11 and for certifying the products pursuant to 21 CFR 1010. It is unlawful for manufacturers to introduce such products into commerce if they fail to comply with the standard or fail to submit reports as required by 21 CFR 1002. No laser product report for your modified device has been received by our office.

Medical devices used by doctors 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). An excimer laser is a class III device under section 513(f) of the Act, and as such it is adulterated under section 501(f)(1)(B) of the Act unless there is a PMA or an investigational device exemption (IDE) in effect for it. This laser is not considered to be covered by Nidek’s PMA. Because an approved PMA or an approved IDE does not cover this laser, it is adulterated within the meaning of the Act. Therefore, you should not be using this laser to treat patients.

It is possible that you could use this device after receiving approval for an IDE application. Please note that, if you were to submit an IDE application to FDA and if FDA were to approve it, you would be able to use the laser to perform only specific procedures on a limited number of patients or subjects to demonstrate the safety and effectiveness of the laser for those procedures. Studies conducted under such an IDE would be subject to all IDE regulations. See 21 CFR Part 812. For example, you would be prohibited from promoting and commercializing the laser, and from representing that the device is safe and effective. In addition, under the IDE regulations, you would also need to obtain approval of your investigation by an institutional review board, to obtain proper informed consent, to maintain records available for inspection by FDA, and to submit reports to the agency. You should be aware that the IDE process is designed to investigate the safety and effectiveness of devices either for research or for marketing authorization, and is not itself a means for commercially marketing devices for treating patients.

Moreover, once the IDE studies are complete, you would not be able to use your laser unless you were to seek a PMA and FDA was to approve it. The agency is aware that physicians with unapproved Nidek lasers may not be able to provide the manufacturing information that is required pursuant to section 515 (c)(1) of the Act to support a PMA, nor to receive Nidek’s written authorization to reference the necessary information from Nidek’s PMA, pursuant to 21 CFR 814.20 (c). If this is the case for you, your IDE would terminate after the collection of safety and effectiveness data and you would not be able to use these data to obtain a PMA for your laser.

It is unlawful to sell unapproved devices in domestic commerce or to export them. The only ways to bring this device into compliance is to destroy or dismantle it (under FDA supervision) or to donate it to an institution for non-human research. Parts from the dismantled laser could be sold for non-medical indications if FDA is provided with appropriate assurances that the parts will never be used in a medical context. This process would require monitoring by the Agency and would have to be completed within a definite timeframe. Any parts that could not be sold within this timeframe would have to be destroyed.

Continued use of your excimer laser, for which neither a PMA or IDE is currently in effect, is unlawful. Please notify us within 15 working days of your receipt of this letter as to what 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 this device to treat patients. Failure to immediately and completely cease use of this device until it is brought 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 civil money 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 or transmitted to her via facsimile at (301) 594-4638. In addition, please send a copy of your response to the Los Angeles District Office of the Food and Drug Administration, 19900 MacArthur Blvd., Ste 300, Irvine, California 92612. If you have further questions, you may call Ms. Davis at (301) 594-4613, extension 127.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Larry Spears".

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health