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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**  
**VIA EXPRESS MAIL**

JUL 11 2001

Paul E. Garland, M.D.  
6005 North Delmonico Drive, Suite #140  
Colorado Springs, Colorado 80919

Dear Dr. Garland:

During an inspection of your medical facility in Colorado Springs, Colorado on May 3 and 4, 2001, our investigator determined that you are using an excimer laser system for refractive surgery, including enhancement procedures that utilize hyperopia or positive diopter re-treatment. Nidek Co., Ltd. in Japan manufactured this laser (serial number 50065) in February 1996, prior to the approval of their premarket approval application (PMA) for the EC-5000 excimer laser.

Subsequent to this inspection, we learned that you may have another unapproved Nidek laser (serial number 50111). Your post-inspection correspondence with Investigator Duong indicated that you are using a Nidek laser at your Denver, Colorado office. You indicated that you have certification from Nidek that this unit was brought up to U.S. approval standards by Nidek Japan, but did not provide copies of this certification.

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. Although your laser (50065) has a long working distance arm installed by Nidek Co., Ltd. while it was in Canada, this laser still contains software version 2.25dhc, which is an [REDACTED] version, not approved for commercial distribution in the United States. This laser does not meet all of the specifications for approval of Nidek's PMA for the EC-5000 excimer laser and is not considered to be covered by that 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.

Nidek's attorney has advised FDA that Nidek does not wish to remanufacture gray market Nidek lasers to bring them into compliance with the specifications of Nidek's PMA approval. Nidek has also not authorized any other firm to re-manufacture these devices to bring them into compliance with the specifications of their PMA.

It is possible that you could use these devices 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 lasers to perform only specific procedures on a limited number of patients or subjects to demonstrate the safety and effectiveness of the lasers for those procedures. Studies conducted under such an IDE would be subject to all IDE regulations. See 21 Code of Federal Regulations (CFR) Part 812. For example, you would be prohibited from promoting and commercializing the lasers, and from representing that the devices are 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 market 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 lasers 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 lasers.

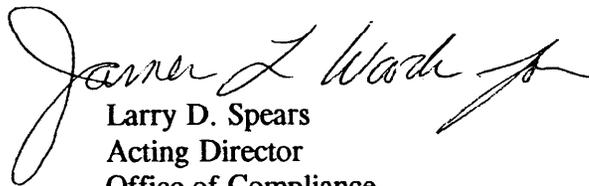
It is unlawful to sell unapproved devices in domestic commerce or to export them. The only ways to bring these devices into compliance are to destroy them (under FDA supervision) or to donate them to an institution for non-human research.

Continued use of your excimer lasers, 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 devices into compliance with the Act. Your response should also clearly state whether or not you have ceased using these devices to treat patients. Failure to immediately and completely cease use of these devices until they are 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.

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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 Denver District Office of the Food and Drug Administration, 6<sup>th</sup> & Kipling Street, Denver, Colorado 80225-0087. 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 D. Spears". The signature is written in black ink and is positioned above the typed name and title.

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