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Via Federal ExpressFood and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 15 1998

Warning Letter

George O. Waring, M.D.
Emory Vision Correction Center
875 Johnson Ferry Road
Atlanta, Georgia 30342

Dear Dr. Waring:

The Food and Drug Administration (FDA) has reviewed a copy of Emory Vision Correction Center's (Emory) advertisement concerning LASIK which appeared in the Tuesday, June 9, 1998, issue of the Atlanta Journal/Constitution (copy enclosed). We have also reviewed information on your internet home page, www.visionforlife.com (copies enclosed). You have been identified as the contact person for Emory; therefore we have addressed this correspondence to you.

The advertisement in question states, "FDA Advisory Panel Unanimously Recommends Approval for LASIK at Emory," and announces upcoming seminars on the LASIK procedure. The statement concerning the advisory panel's recommendation is misleading: The advertisement misrepresents the facts of the advisory panel's recommendation and implies that the advisory panel recommends and FDA will approve the [REDACTED] laser for the LASIK procedure at Emory. The statement also implies that Emory has a legally marketed [REDACTED] laser approved for LASIK. For your information, FDA does review and take into consideration the advisory panel's report and recommendation; however, the advisory panel's report and recommendation is not the approval order. It is FDA that issues the final approval or non-approval order.

The [REDACTED] System [REDACTED] is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). It is an investigational device for the LASIK procedure and does not have commercial marketing approval until it achieves full approval with or without conditions from the Agency. Therefore, until you receive an approval letter from the FDA your laser continues to be an investigational device when used for LASIK procedures. Title 21 Code of Federal Regulation (21 CFR) 812.7 prohibits a sponsor, investigator, or any person acting for or on their behalf, from promoting an investigational device until after FDA has approved the device for commercial distribution.

For your convenience we have enclosed printed copies of your internet pages that contain statements and implications which constitute serious violations of FDA

Page 2 – George O. Warning, M.D.

regulations pertaining to the advertisement and promotion of an investigational device. The "Current Patient Newsletter" also contains a paragraph regarding expansion of the LASIK system capabilities, an area not considered in your PMA submission. Moreover, the disclaimer regarding FDA and FTC prohibition in your description of the LASIK procedure cannot compensate for the safety and effectiveness statements included, particularly under the heading of "Advantages."

Although FDA encourages the full exchange of scientific information concerning investigational devices, including dissemination of scientific findings through scientific and medical publications or conferences/seminars, you may not make representations that the device is safe and effective for the purposes for which it is being investigated. Until devices have received Agency approval for specific indications, their use, including demonstration and teaching to persons not associated with an approved Investigational Device Exemption (IDE), is regarded as promotional.

For your information, the Premarket Approval Application (PMA) that you submitted is ONLY for the one particular [REDACTED] laser unit that was studied at Emory. Furthermore, Emory should not be recruiting subjects for their IDE on the [REDACTED] unit because enrollment was ceased and the unit is supposed to be in storage.

This letter is not intended to be an all-inclusive list of the violations noted. It is your responsibility to ensure adhere to each requirement of the regulation.

Please inform us, in writing, within 15 days of receipt of this letter, as to the corrective measures you have taken to ensure that this advertisement and all similar ones are removed from distribution and that the public is made aware of the errors implied in Emory's printed statement. Also, please inform us of your actions to remove prohibited statements from your internet information. **Furthermore, you may not announce at your seminars that the FDA panel approved your PMA for LASIK.** Failure to promptly correct these violations may result in further regulatory action by FDA without further notice. These actions include, but are not limited to, injunction, seizure, and/or civil money penalties.

Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D.

Page 3 – George O. Warning, M.D.

If you have any questions or concerns, please call Jean Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,



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

Enclosures