Morris Waxler, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ401)
9200 Corporate Blvd.
Rockville, MD 20850

IDE: G970088

To Dr. Waxler:

On July 28, 1997, FDA requested additional information regarding my investigational device exemption (IDE) application for a Sullivan excimer laser system (which I refer to in my IDE application as Nevyas Excimer Laser and hereafter refer to as "the laser") for use in refractive eye surgery. This letter responds to FDA's request for additional information.

Since the close of business on July 28, 1997, neither I nor anyone else has used the laser. I certify that, unless and until FDA approves the IDE application for that device, neither I nor anyone else will use the laser to treat patients. I have notified all of my employees, as well as anyone with access to the laser, that the laser may not and will not be used until there is an approved IDE in effect for that laser.

I declare that to the best of my knowledge the foregoing is true and correct.

Executed on 8/6, 1997.

Sincerely,

FDA C083