DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 1997

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK for Myopia (-0.5 to -22 Diopters with up to -7 D Astigmatism)
Dated: March 18, 1997
Received: April 8, 1997

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. We regret to inform you that your application is disapproved and you may not begin your investigation. Our disapproval is based on the deficiencies listed below. Because your excimer laser system, which you have told us is being used to treat patients, has neither an approved application for premarket approval (PMA) under section 515(a) of the Federal Food, Drug and Cosmetic Act (the Act), nor an IDE under section 520(g), your device is adulterated under section 501(f)(1)(B). This is to advise you that, consequently, any use of these devices to treat patients is a violation of the law.

Our disapproval of your IDE is based on the following deficiencies:

1. On page 22 you indicate that cadaver eyes were ablated with the laser and topography measurements were taken to verify uniformity of ablation. Since your submission contains no actual ablation profiles (other than the theoretical ablation patterns in Attachment 3.4.1.3.A-1) which show that the laser can actually function as designed, please provide the corneal topographies of the cadaver eyes, or provide corneal topographies from your previous clinical studies.

2. You have not provided a sufficiently detailed scientific and technical analysis of the following critical engineering aspects of your device. Please provide this information for each refractive indication being studied: