DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2002

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

Re: G970088/S25
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: March 26, 2002
Received: March 27, 2002
Next Annual Report Due: August 7, 2002

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the additional information for your annual progress report to your investigational device exemptions (IDE) application and has determined that additional information is required.

Please address the following questions and concerns with regard to this submission:

1. You must still provide responses to deficiencies 1, 2, 3, and 5 from our letter of February 6, 2002.

2. You did not provide the requested information in your response to deficiency 4.

   a. For the eye with the central, corneal infiltrate noted at the 1-month visit, please report the eye's preoperative BSCVA, how the infiltrate was managed (i.e., cultures, antibiotics administered, etc.), when the infiltrate resolved, and the final BSCVA.

   b. In addition, you stated, "The observation was omitted from the 2001 Annual Report because the adverse event listing is 'corneal infiltrate or ulcer at 1 month or later' and the observation actually occurred earlier than 1 month postoperatively (although the infiltrate was noted at the 1-month visit, 25 days postoperatively)." We would like to point out that the FDA interprets "1 month or later" to mean within the 1-month visit window or later. This is true as well for all other time point references made in the protocol. Please keep this in mind when preparing all other future submissions to the FDA.