DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2001

APR 10 2001

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

Re: G970088/S18
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 14, 2001
Received: March 16, 2001
Next Annual Report Due: August 7, 2001

Dear Dr. Nevyas:

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

Please address the following questions/concerns, as well as provide the information requested in the tables enclosed with this letter.

1. You have stated that, for the safety and efficacy analyses, the "N" used as the denominator when calculating percentages was the actual number of patients completing each visit. The "N" should be the number of eyes that completed the particular evaluation being analyzed at that visit. For example, if a subject, who had bilateral treatment, was available for analysis at the 1-month follow-up visit, but did not undergo manifest refraction, this subject's 2 eyes would not be included in the "N" (or the "n", numerator of the percentage calculation) for the BSCVA analysis. Please adjust the tables accordingly, if necessary.

2. The only protocol deviations reported were that "some" visits were completed outside the visit windows. Visits falling outside the visit window should not be included in the analyses at that particular visit, but should be analyzed separately. Please revise your tables accordingly including the accountability tables.

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3. Please provide stability analyses and indicate the point of stability for each indication (see enclosed tables).

4. You have reported the percentage of eyes losing more than 2 lines of BSCVA. This should be the percentage of eye losing more than or equal to 2 lines of BSCVA.