DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 2002

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

Re: G970088/S24
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: January 5, 2002
Received: January 8, 2002
Next Annual Report Due: August 7, 2002

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 and concerns with regard to this submission, which also applied to the previous, delinquent, annual report as outlined in FDA's letter of April 10, 2001, and for which we never received a response:

1. When reporting protocol deviations, you indicated that some subjects had study visits that were late. For each time point, please clarify how many eyes had visits that fell outside of the visit window. Please clarify how far outside of the visit window each of these visits fell. 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.

2. For each eye that experienced a loss of 2 or more lines of BSCVA at 6 months or later postoperatively and for each eye that had BSCVA worse than 20/40 at 6 months or later, please provide a dataline listing and an explanation for the vision loss or vision. Please include a narrative for each case discussing any other visual or non-visual symptoms, the management, and the outcome. Please group this information according to the 4 indications for treatment in this protocol.

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