DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

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

Re: G970088/S17
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: October 8, 1999
Received: October 12, 1999
HCFA Category: A-2
Next Annual Report Due: August 7, 2000

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:

1. Please separate IDE subjects from pre-IDE subjects in all of your tables, or report only on IDE subjects.

2. Please include an accountability table, similar to the one presented by you in last year's annual report, showing completed visits, missed visits, etc. for each visit time for all eyes. You should account for all eyes treated in the IDE.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

FDA 0 0054