DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 7 1997

Re: G970088/A1, A3 and A4
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK for Myopia (-0.5 to -6.75 Diopters with up to -7 D Astigmatism)
Dated: July 3, 21, and 29, 1997
Received: July 8 and 22, and August 1, 1997
HCFA Reimbursement Category: A2 (for procedures to request re-evaluation of this categorization decision, please see the appropriate enclosure)
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the amendments to your investigational device exemptions (IDE) application. Your application is conditionally approved because you have not adequately addressed deficiency #2 cited in our May 8, 1997 disapproval letter. You may begin your investigation, using a revised informed consent document which corrects deficiency #1 (below), after you have obtained institutional review board (IRB) approval, and submitted certification of IRB approval to FDA. Also, we are in receipt of your certification (Amendment 4 received August 1, 1997) that you have not used the laser as of the close of business on July 28, 1997, and that you will not use the laser unless and until FDA approves the IDE application for your device. You are reminded that when the agency has approved (conditionally or otherwise) an IDE for a device, all treatments with that device after the date of FDA approval of the IDE are treatments under the IDE; consequently, the device may be used to treat only the number of subjects approved in the IDE and only for the indications approved in the IDE. Your investigation is limited to one institution and 100 subjects for Low Myopia (-0.5 to -6.75 D) plus Astigmatism (up to -7 D).

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies:

FDA 0 0016

1. Since your ablations are clearly non-spherical, as well as multifocal, you should provide a much stronger caution to your prospective subjects regarding the ability to see well in low light level situations. Please amend the risk section of your informed consent document with additional [illegible] "You probably will not be able to see as well in situations