DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 2 8 1998

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 1998

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

Re: G970088/S12
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.
Dated: August 24, 1998
Received: August 27, 1998
Next Annual Report Due: August 7, 1998 (Extension granted to September 21, 1998)

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application addressing deficiencies in our July 7, 1998 letter regarding myopia and myopia plus astigmatism retreatments and addressing the deficiency in our letter of May 14, 1998 regarding validation of your glare source for contrast sensitivity testing. Your supplement proposing an expansion of your study for myopia and myopia plus astigmatism retreatments is approved. Your supplement regarding contrast sensitivity testing is conditionally approved. You may continue your investigation at the institution enrolled in your investigation. Your investigation is limited to 1 institution and 225 subjects: 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 50 subjects (100 eyes) for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiency: FDA 0 0045

In the validation of your glare source for the contrast sensitivity study, you tested subjects at 2.5 cd without glare and at 2.5 cd with glare of 2 lux. The light level of 2.5 cd appears to be appropriate, since a change is demonstrated for the different