DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: G970088/S6
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK 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 enhancement to correct myopia of eyes previously treated with this laser
Dated: December 11, 1997
Received: December 15, 1997
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing a plan for simultaneous bilateral LASIK. Your supplement is conditionally approved, and you may implement that change at the institution enrolled in your investigation. Your application remains conditionally approved because you have not addressed the deficiencies cited in our December 16, 1997 letter. You may continue your investigation at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 institution and 150 subjects: 100 subjects for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 25 subjects for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects for enhancements of previously treated subjects (-0.5 to -15 D myopia with up to -7 D astigmatism).

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:

In your "Substudy for Same-Day Versus Different Day LASIK Treatment for Fellow Eyes":

FDA 0 0034

a. Please revise your informed consent document rider for same day surgery to state that the second eye will be rescheduled if there is a complication or an adverse event with the first eye.