DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

DEC 16 1997

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

Re: G970088/S5
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: November 12, 1997
Received: November 17, 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. Your application remains conditionally approved because your supplement adequately addressed only deficiency 2 cited in our October 3, 1997 letter. You may continue your investigation at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to one 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:

1. You have stated that you currently are working on plans for a fail-safe mechanism for your device. Please submit an engineering plan and time-table for retrofitting your device with an adequate fail-safe mechanism. This mechanism should include a safe means to complete the treatment.

FDA 0 0032

2. Regarding retreatments (enhancements), your data do not appear to support enhancement after 8 weeks postoperatively. It is possible that there is merely a matter of differences in interpreting your data. Please provide your stability data according to the tables enclosed (see enclosure, "Stability of Manifest Refraction"). Also, please submit a retreatment study plan. You may begin retreatment procedures only after FDA has reviewed that data and approved your retreatment study plan.