DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

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

Re: G970088/S2, S3, and S4
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: August 28, September 10 and September 19, 1997
Received: September 9, 12, and 22, 1997
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed supplements 2, 3 and 4 to your investigational device exemptions (IDE) application. Supplement 2 requests a protocol deviation to treat two anisometropic patients (one eye at -10 D and one eye at -7.50 D); you were granted permission by telephone on September 9 to treat these two anisometropic patients. We acknowledge receipt of your institutional review board (IRB) approval (supplement 3). Supplement 4 responds to our conditional approval letter of August 7, 1997 and requests: an increase in treatment range from -6.75 D to -22 D; approval to study simultaneous bilateral treatment; and, approval to retreat approximately 125 patients previously treated with this laser prior to IDE approval.

FDA cannot approve your request to study LASIK in higher myopes up to -22 D because you have not provided adequate data to support safe use above -15 D. FDA will conditionally approve, however, a study at this time of LASIK in 25 subjects with myopia -7 D to -15 D with up to -7.00 D of astigmatism; please see the conditions of approval below. If you agree to conduct your investigation within the modified limit, you may implement that change at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. If you do not agree to this modified limit, you should consider this letter as a disapproval of your request for an expansion of the investigation, and you have an opportunity to request a regulatory hearing as described in the enclosure "Procedures to Request a Regulatory Hearing."

FDA 0 0021

FDA cannot approve your request to study enhancements on up to 125 of your prior clinical patients, because you have not provided adequate preliminary data to demonstrate safety of,