DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 09 2001

JAN 30 2001

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

Re: G970088
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of –0.5 to –15 Dipoters (D) with up to –7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) granted approval of your investigational device exemptions (IDE) application on August 7, 1997. As part of your responsibilities as sponsor of a significant risk device investigation, you are required to submit a progress report to FDA and to all reviewing institutional review boards (IRBs) on at least a yearly basis. We have not received a response to FDA's November 10, 1999 request for additional information regarding your August 1998 – August 1999 annual progress report (enclosed). In addition, please provide your annual progress report for the year August 1999 – August 2000.

Please submit your response to FDA's November 10, 1999 letter and your year 2000 annual progress report to FDA within 45 days from the date of this letter. The information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide the requested information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

FDA 0 0056