MAY 2 0 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 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/S8 & S9
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 enhancement to correct myopia of eyes treated with this laser prior to IDE approval.
Dated: April 12 and 14, 1998
Received: April 14 and May 8, 1998
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplements to your investigational device exemptions (IDE) application. Supplement 8 proposed a plan for a contrast sensitivity substudy and provided a design for a fail-safe mechanism, and Supplement 9 requested additional high myopia subjects. Your plan for a contrast sensitivity substudy is conditionally approved, and you may implement that change at the institution enrolled in your investigation. Your design and time-table for a fail-safe mechanism is approved. Your request for additional high myopia subjects (- 7 to -15 D with up to -7 D astigmatism) is approved for an additional 25 subjects (50 eyes). In addition, your application is approved for an additional 50 subjects (100 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism).

Your application is approved because you have 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 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).

FDA 0 0039

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 (contrast sensitivity substudy) in your investigation (21 CFR 812.35(a)).