DEC 0 7 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 - 1998

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

Re: G970088/S13
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 retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: October 30, 1998
Received: November 2, 1998
HCFA Category: A-2
Next Annual Report Due: August 7, 1999

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing an accommodation substudy to address multifocality of the LASIK ablation. Your supplement is approved, and you may implement that change at the institution enrolled in your investigation. Your investigation is limited to one institution and 225 subjects (450 eyes): 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).

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

Please be aware that we now believe your proposed mesopic contrast sensitivity study will adequately address deficiency 14 of our letter of October 7, 1997, without the need for a test of the multifocal properties of your ablation, such as your proposed test for change in accommodation. The reason for this is that the contrast sensitivity test may provide adequate information to label your device properly.

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