



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

 Food and Drug Administration
 9200 Corporate Boulevard
 Rockville MD 20850

JAN 20 1999

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

Re: G970088/S15
 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: January 5, 1999
 Received: January 6, 1999
 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 providing validation data for the contrast sensitivity study. You have corrected the deficiency cited in our September 24, 1998 conditional approval letter. Your application is approved, and you may continue your investigation at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. Your investigation is limited to one institution and 1015 subjects (2030 eyes); 990 subjects (1980 eyes) for myopia (-0.5 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).

Please be aware of the following:

In Table 1-1, the data appear to be quite scattered, with some subjects actually increasing in sensitivity during glare (e.g., see BC & CB at 3 cycles per degree (CPD)), while others are severely compromised (see ZM). In order to reduce variability in the data in the contrast sensitivity study, the person administering the test should have experience in this test and the subjects should be well trained prior to testing.

FDA 0 0052