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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

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

Re: G970088/A1 and A3
Device name: Sullivan Excimer Laser System (Nevyas Model)
Dated: July 3 and 21, 1997
Received: July 8 and 22, 1997

Dear Dr. Nevyas:

On July 8 and 22, 1997, the United States Food and Drug Administration (FDA) received the amendments to your investigational device exemption (IDE) application that you submitted for your excimer laser system for use in refractive eye surgery. FDA has started to review this application. We have determined, however, that additional information is required in order to complete this review.

Excimer laser systems are Class III devices within the meaning of section 513(f) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, a physician may not use an excimer laser system to treat patients unless there is in effect an approved premarket approval application (PMA) or an approved IDE for that device.

FDA is aware that a number of physicians are using lasers for refractive surgery to treat patients even though there is no PMA or IDE in effect for their lasers. Based on the results of our investigations, we believe that you are currently using your laser to treat patients.

FDA 0 0013