



JUL 25 2001

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

Re: G970088/S20  
Sullivan Excimer Laser System (Nevyas Model)  
Dated: June 21, 2001  
Received: June 25, 2001  
Next Annual Report Due: August 7, 2001

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing two new clinical protocols to evaluate the spherical ablation algorithm. We regret to inform you that your supplement is disapproved and you may not implement the change in your investigation. Our disapproval is based on the following deficiencies which, unless otherwise specified, relate to both protocols:

1. You have stated that subjects will be evaluated preoperatively and 1 day, 1 week, and 1, 3, and 6 months post-LASIK, and that a final exam will be conducted at least 3 months after the time when refractive stability is achieved. For new indications, where the time point of stability is not established, we recommend 24 months of follow-up. We consider all indications using the new, spherical ablation algorithm to be "new" indications. Please revise your protocol, case report forms, and consent form accordingly, or justify not doing so. Please add evaluations for each study eye at 9, 18, and 24 months postoperatively regardless of the individual subjects' postoperative refractive stability. You may request to modify your protocol if the preliminary data indicate earlier stability of the cohort. Please note that the point of stability may differ for different refractive indications, e.g., low spherical myopia only, high spherical myopia only, low myopia with astigmatism, high myopia with astigmatism, spherical hyperopia, and hyperopia with astigmatism.
2. You have identified target values at the "mean time of stability" and you have defined stability as "two manifest refraction spherical equivalent (MRSE) measurements taken at two consecutive visits that are at least 2 to 3 months apart that are within 1.0 D of each other". The FDA normally evaluates target values at the point of stability defined as the time point when 95% of the eyes have a change of  $\leq 1D$  of MRSE between 2 refractions performed at least 3 months apart. Please revise your protocol in order to be consistent with the FDA's definitions.

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