DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 16 2001

Re: G970088/S22
Nevyas Excimer Laser
Dated: July 20, 2001
Received: July 23, 2001
Annual Report Due: August 7, 2001 (overdue)

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing the validation for Appollo Software. 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:

1. An important function of the software in the device is to control the beam delivery hardware (iris size, slot movement, synchronizing iris/slot with laser pulses, etc.) in the creation of an ablation pattern. This area, however, is not discussed at all in the Software Requirement Specifications document. Please provide a step-by-step description, from the very first pulse to the last pulse, of how the ablation pattern(s) to be used in this study is(are) to be created by the device. This description should include specific values for the starting size for the iris, starting position for slot, the amount to incremental change for iris or slot, etc.

2. The provided Hazard Analysis and Test Data appear to be limited to the user-interface function of the software. Given all the functions of the software, please identify those that are either safety critical or safety-related (see the Checklist of Information Usually Submitted in an IDE for Refractive Surgery Lasers, section 3.4.1.3 D, available at http://www.fda.gov/cdrh/ode/2093.html), and discuss how those safety functions were validated.

3. The Revision History Log is only up to version 3.22. Please update it to include all revisions up to version 3.66, which appears to be the latest version for the software.

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