Supplement No. 13 -- Annual Report IDE #G970088 (Nevyas Excimer Laser) November 4, 1998

1.0 STUDY PROGRESS

Clinical data summarized in this annual report are for those subjects whose data are entered in the database as of October 1, 1998. The database has been reviewed for obvious errors and omissions but the data is otherwise unaudited. Individual summaries of the study progress for NEV-97-001 and Substudy NEV-97-002 are provided below.

- 1.1 PROTOCOL NEV-97-002 -- LASIK for Myopia with or without Astigmatism (-0.5 D to -22.00 D sphere; 0 to -7.0 D cylinder)
 - A. STATUS: Ongoing
 - B. NUMBER OF INVESTIGATORS: Two

 This remains a single site study which is being conducted by the joint sponsorinvestigators:

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- C. NUMBER OF SUBJECTS ENROLLED:
 - 1. Number of Subjects Enrolled: 95 Subjects (Low Myopia < -7.0 D)

46 Subjects (High Myopia ≥ -7.0 D) 10 Subjects (Pre-IDE Enhancements)

2. First Date of Enrollment: August 28, 1997

D. NUMBER OF DEVICES SHIPPED:

Not Applicable. The device was assembled on-site at Nevyas Eye Center. No additional devices have been shipped or assembled.