1.2 Substudy NEV-97-002: Changes in Contrast Sensitivity in Patients Undergoing LASIK Treatment with the Nevyas Excimer Laser

A. Substudy to Protocols: NEV-97-001 (Myopia/Myopic Astigmatism)

B. STATUS: Not Started

C. NUMBER OF INVESTIGATORS: Two

This remains a single site study which is being conducted by the joint sponsor-investigators:

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D. NUMBER OF SUBJECTS ENROLLED:

1. Number of Subjects Enrolled 0

E. NUMBER OF DEVICES SHIPPED:

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

F. SUMMARY OF CLINICAL RESULTS

A validation of the glare source was performed by the manufacturer of the glare tester (Stereo Optical). Upon review of the data, FDA believed the glare source of 2 lux to be too bright. Validation using a glare sources with a smaller lux is underway.

G. PROTOCOL DEVIATIONS

Not applicable

H. SUMMARY OF COMPLICATIONS AND ADVERSE EVENTS:

Not Applicable