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

## 5.0 Progress towards PMA Approval

Target date for submission of the PMA is 1st Quarter of 1999. The data for Protocol NEV-97-002 will be used to submit the PMA for the indications of myopia and myopic astigmatism. The data for this study were reviewed extensively during preparation of this annual report to determine what data were missing or outstanding from co-management physicians. The data have not been audited but will be audited prior to completing the data analyses for the PMA.