Table 1.1.E-4: Comparison of LASIK Safety and Efficacy Criteria at 3 Months Postoperatively.

Parameter	LASIK Low Myopia	LASIK High Myopia	Nevyas Excimer Laser 3 Months Postop
Percentage of eyes with UCVA of 20/40 or better if BSCVA 20/20 or better preoperatively*	85%	75%	87.1% Low Myopia 74.2% High Myopia
Percentage of eyes achieving refractive predictability (attempted versus achieved) that are within:			
± 0.50 D	50%	30%	71.3% Low Myopia 37.1% High Myopia
± 1.00 D	75%	60%	85.1% Low Myopia 61.3% High Myopia
± 2.00 D	NA	90%	98.9% Low Myopia 82.3% High Myopia
Percentage of eyes losing more than 2 lines of BSCVA	< 5%	< 5%	0.0% Low Myopia 0.0% High Myopia
Percentage of eyes that have BSCVA worse than 20/40 if BSCVA 20/20 or better preoperatively	< 1%	< 1%	0.0% Low Myopia 0.0% High Myopia

*Nevyas Excimer Laser data not stratified by preoperative UCVA

The 3 month postoperative data for eyes treated for low myopia surpasses the LASIK safety and efficacy criteria for low myopia. The high myopia data nearly meet the FDA criteria for UCVA without stratifying for preoperative BSCVA. The percentage of high myopia eyes that are within ± 0.50 D and ± 1.00 D of the attempted versus achieved refractions is greater than the proposed recommendations for high myopia. The percentage that are within ± 2.00 D is lower than the high myopia recommendations but is expected to improve over time as are the number of high myopia eyes that have an UCVA of 20/40 or better.

F. PROTOCOL DEVIATIONS:

Patient accountability is provided in Table 1.1.E-1 above. Outstanding follow-up visit information is still being collected from the co-management doctors. No other protocol deviations were reported.