G. SUMMARY OF COMPLICATIONS AND ADVERSE EVENTS:

Complications and adverse events that occurred in the study are summarized in the tables below. The only reported complications were related to the microkeratome and creation of the corneal flap during the LASIK procedure. Of the 5 reported microkeratome-related complications, there were 2 reports of an irregular flap, 1 report of a torn hinge, and 2 reports of an incomplete traverse of the microkeratome.

Table 1.1.G-1: Complications Summary Table

COMPLICATION	Intra-operative n/N (%) N = 230	1 Month n/N (%) N = 168	3 Months n/N (%) N = 156	6 Months n/N (%) N = 80	9 Months n/N (%) N = 18	12 Months n/N (%) N = 7
Corneal edema between 1 week and 1 month after the procedure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Peripheral corneal epithelial defect at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Epithelium in interface	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Foreign body sensation at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pain at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ghost/double images in the operative eye	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Flap is not of the size and shape as initially intended or microkeratome stopped in mid-cut	5 (2.2)%	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

N = number of eyes completing the postoperative visit