

**Summary of Safety and Effectiveness Data
For a Supplemental Premarket Approval Application**

I. GENERAL INFORMATION

Device Generic Name: Ophthalmic Excimer Laser System

Device Trade Name: LADARVision® Excimer Laser System

Applicant's Name and Address: Autonomous Technologies Corporation
2800 Discovery Drive
Orlando, FL 32826

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P970043/S5

Date of Notice of Approval to Applicant: May 9, 2000

The LADARVision® Excimer Laser System was approved on November 2, 1998 for the indication of photorefractive keratectomy for the reduction or elimination of mild to moderate myopia of between -1.00 and -10.00 D sphere and less than or equal to -4.00 D astigmatism at the spectacle plane, the combination of which must result in an attempted correction of between -0.50 and -10.00 D spherical equivalent at the spectacle plane where the sphere or cylinder is at least 1.00 D (P970043). The sponsor submitted the current supplement to further expand the indication statement. The updated pre-clinical and clinical work to support this expanded indication is provided in this summary. For more information on the data that supported the approved indication, the Summary of Safety and Effectiveness Data to that PMA application should be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Please identify Docket # OOM-1592. The summary can also be found on the FDA CDRH Internet Home Page located at <http://www.fda.gov/cdrh/pmapage.html>.

**TABLE 16:
CHANGE IN SYMPTOMS POSTOPERATIVE FROM PREOP**

n %	Significantly Better	Better	No Change	Worse	Significantly Worse	Question NR*	No QE**	Total
Light Sensitivity	36 10.6%	43 12.7%	183 54.0%	67 19.8%	10 3.0%	0	8	347
Headache	30 8.9%	41 12.1%	244 72.0%	23 6.8%	1 0.3%	0	8	347
Pain	46 13.7%	36 10.7%	247 73.3%	8 2.4%	0 0.0%	2	8	347
Redness	41 12.1%	52 15.3%	227 67.0%	15 4.4%	4 1.2%	0	8	347
Excessive Tearing	40 11.8%	32 9.5%	258 76.3%	8 2.4%	0 0.0%	1	8	347
Burning	37 11.0%	42 12.4%	246 72.8%	13 3.9%	0 0.0%	1	8	347
Gritty Feeling	46 13.6%	43 12.7%	231 68.1%	19 5.6%	0 0.0%	0	8	347
Glare	24 7.1%	46 13.6%	161 47.5%	88 26.0%	20 5.9%	0	8	347
Halos	18 5.3%	48 14.2%	173 51.0%	84 24.8%	16 4.7%	0	8	347
Dryness	20 5.9%	62 18.3%	175 51.6%	69 20.4%	13 3.8%	0	8	347
Night Driving Difficulty	29 8.6%	73 21.6%	128 37.9%	76 22.5%	32 9.5%	1	8	347
Blurring of Vision	56 16.5%	55 16.2%	169 49.9%	52 15.3	7 2.1%	0	8	347
Double Vision	36 10.7%	25 7.4%	254 75.2%	19 5.6%	4 1.2%	1	8	347
Fluctuation of Vision	36 10.7%	48 14.2%	178 52.7%	67 19.8%	9 2.7%	1	8	347

*NR= No response to question; ** No QE= Questionnaire not performed

A subgroup study on contrast sensitivity testing was performed at 2 sites. Preoperative and 6-month postoperative data from 212 myopic eyes was analyzed. However, results were unreliable and no conclusions could be made.