SUMMARY OF SAFETY AND EFFECTIVENESS
FOR A SUPPLEMENTAL PREMARKET APPLICATION

I. GENERAL INFORMATION

Device Generic Name: Ophthalmic Medical Laser System
(193 nanometer wavelength)

Device Trade Name: LaserSight LaserScan LSX Excimer Laser System

Applicant's Name and Address: LaserSight Technologies, Inc.
3300 University Blvd., Suite 140
Winter Park, Florida 32792
(407) 678-9900

Premarket Approval (PMA) Application Number: P980008/S5

Date of Panel Recommendation: None

Date of Notice of Approval to Applicant: September 28, 2001

The LaserScan LSX Excimer Laser was approved on November 12, 1999 under P980008 for the indication of photorefractive keratectomy for the reduction or elimination of myopia ranging from –1.0 to less than –6.0 diopters (D) with less than or equal to 1.0 D of astigmatism. The sponsor submitted the current supplement to further expand the indication statement. The updated clinical data to support this expanded indication are provided in this summary. The pre-clinical test results were presented in the original PMA application. For more information on the data that supported the approved indication, the summary of safety and effectiveness data (SSED) for P980008 should be referenced. Written requests for copies of the SSED can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. The summary can also be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html.

II. INDICATIONS FOR USE

The LaserScan LSX Excimer Laser is intended for laser-assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of myopia ranging from –0.5 to less than –6.0 diopters (D) spherical equivalent, with astigmatism less than or equal to 4.5 D, as measured at the spectacle plane;

- in patients with documentation of a stable manifest refraction defined as $\leq$ 0.50 D, or $\leq$ 10% of preoperative spherical equivalent refraction (SER) shift over one year prior to surgery; and,

- in patients who are 18 years of age or older.

III. CONTRAINDICATIONS

Patients with the following conditions should not be considered for LASIK surgery:

- Active ocular / systemic infection in operative eye;
- Fuch's corneal dystrophy in either eye;
- Keratoconous in either eye;
- Central corneal scars affecting visual acuity;
- Autoimmune or immunodeficiency diseases;
- Pregnant or nursing women; or,
- Taking one or both of the following medications: isotretinoin (Acutane) and amiodarone hydrochloride (Cordarone)

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the labeling.

V. DEVICE DESCRIPTION

The LaserSight LaserScan LSX Excimer Laser System (henceforth, to be called the LSX) that is the subject of this supplement differs from the unit previously approved for PRK in the amount of correction to be provided for a given refractive error (i.e., different treatment nomograms for LASIK and PRK). Except for that one nomogram difference, the other ablation characteristics (e.g., fluence, repetition rate, and shot placement) remain the same.

The operative laser parameters are summarized as follows.

LaserScan LSX Excimer Laser Parameters		
Pulse Rate: 100 Hz Fluence: 80 - 100 mJ/cm		
Ablation Zone Size		
SER	Maximum Ablation Zone (mm)	Maximum Transition Zone (mm)
< 6.0 D	6.0	7.0

The LASIK procedure requires the use of a commercially available microkeratome that has been cleared for marketing via premarket notification. The device used in this study consists of a sterilization/storage tray, which includes the shaper head, a left/right eye adapter, suction ring, suction handle, blade handling pin, and corneal reference marker. The instrument motor, tonometer, cleaning brush, disposable blades, power/suction supply unit with vacuum and motor footswitches and power cords are provided as separate components in an accessory stand and equipment suitcase which complete the system.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Conventional methods in correcting nearsightedness with and without astigmatism are: spectacles, contact lenses, PRK, or other types of refractive surgery.

VII. MARKETING HISTORY

Over 150 LSX have been installed in the following countries:

Argentina	Costa Rica	India	Norway	The Netherlands
Australia	Dom. Republic	Israel	Pakistan	Turkey
Belgium	Egypt	Italy	Peru	Yugoslavia
Brazil	England	Korea	Portugal	
Canada	Finland	Malaysia	Romania	
China	France	Mexico	South Africa	
Columbia	Guatemala	Namibia	Spain	

The LSX has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VIII. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects associated with LASIK include: loss of best spectacle corrected visual acuity, overcorrection, increase in refractive cylinder, abnormal glare, double vision, sensitivity to bright lights, difficulty with night vision, increase in intraocular pressure, corneal haze, corneal infection/ulcer/infiltrate, corneal decompensation/edema, lens abnormality and secondary surgical intervention, problems associated with the flap, including a lost, misplaced or misaligned flap, retinal detachment, and retinal vascular accidents.

Please refer to the complete listing of adverse events and complications observed during the clinical study, which are presented in the clinical study section.

IX. SUMMARY OF PRECLINICAL STUDIES

No additional preclinical studies were required for the use of the device for LASIK. Please refer to the SSED of the original PMA P980008.

X. SUMMARY OF CLINICAL STUDY

The sponsor performed a prospective clinical trial in healthy eyes at ten US clinical sites under investigational device exemption (IDE) application # G980248. The data from this study served as the basis for the approval decision. Specifically, safety and effectiveness outcomes at 6 months postoperatively were assessed, as stability was reached by that time. Outcomes at 12 months postoperatively were also evaluated for confirmation of stability. The IDE study is described in detail as follows:

A. Study Objectives

The objectives of the study were to determine the safety and effectiveness of the LSX for LASIK treatment of spherical equivalent refraction (SER) of up to -15.00 D (–0.50 to –15.00 D of myopia with and without astigmatism of –0.50 to –6.00 D) and to assess stability of the achieved visual outcome.

B. Study Design

The study was a prospective, non-randomized, 10 center, and 23 surgeon study where the primary control was the preoperative state of the treated eye (i.e., comparison of pretreatment and post-treatment visual parameters in the same eye).

C. Inclusion and Exclusion Criteria

Study subjects were 18 years or older and had signed an informed consent. Enrollment occurred if the subject met these conditions: -0.50 to –15.00 D SER and spherical myopia with astigmatism up to 6 D; best spectacle corrected visual acuity (BSCVA) of 20/25 or better in the operative eye, normal corneal topography and stable manifest refraction as documented by $\leq$ 0.5 D change or $\leq$ 10% of (SER) shift within twelve months prior to surgery. Contact lens wearers had to refrain from contact lens use prior to baseline examination (2 weeks for soft / gas permeable lenses, 3 weeks for hard lenses).

Subjects not meeting the above inclusion criteria were excluded from the study. In addition, subjects who exhibited any of the following conditions were excluded: keratoconus, active ocular disease or corneal abnormality, corneal neovascularization within 1 mm of the intended ablation zone, systemic disease likely to affect wound healing, unstable keratometry readings with irregular shaped mires or corneascope photographs with broken central rings, use of systemic medications likely to affect wound healing,immunodeficiency, previous intraocular or corneal surgery, glaucoma or glaucoma suspect, corneal thickness that would require ablation within 250 microns of endothelium, sensitivity to study medications, pregnancy/lactation, and participation in another ophthalmic trial within the past 30 days.

D. Study Plan, Patient Assessments and Efficacy Criteria

Subjects were evaluated preoperatively and postoperatively at day and week one and at months 1, 3, 6, and 12. Pre-operative objective measurements included: uncorrected and best corrected visual acuity, manifest or cycloplegic refraction, keratometry, intraocular pressure, pachymetry, clinical assessment of corneal clarity, clinical assessment of anterior chamber, vitreal, retinal and lens status, assessment of complications and adverse reactions, and assessment of pupil size in mesopic (dim) conditions.

Additionally, corneal topography was performed pre-operatively to rule out corneal abnormalities, such as keratoconus.

Subjects were permitted to have second eyes (fellow eyes) treated at the same time as the first eye (primary eye). In addition, subjects were eligible for retreatment if the treated eye remained undercorrected and /or regression decreased the uncorrected vision to 20/30 or worse and the eye had a stable refraction.

Effectiveness was evaluated based on improvement in uncorrected visual acuity, reduction in mean spherical equivalent refractive error, and stability of refractive outcome through the postoperative period, and in terms of accuracy of correction. Descriptive statistics were provided on data up to 6 months.

The primary efficacy variables for this study were improvement of UCVA and accuracy of manifest refraction spherical equivalent (MRSE).

E. Study Period, Investigational Sites and Demographic Data

1. Study Period

A total of 204 eyes in 109 subjects were treated between August 17, 1999 and June 20, 2000. The database for this PMA supplement reflected the data collected through June 30, 2000.

2. Demographics and Baseline Characteristics

The demographics of this study population are very typical of a contemporary refractive surgery trial performed in the US. The cohort consists primarily of Caucasians. The majority of subjects were male. The mean age was 39.8 years at the time of surgery. Preoperative patient characteristics that were found to associate with outcomes are discussed in section X.F.2.f (Factors Associated with Outcomes).

Table 1 Demographic Characteristics 109 subjects (204 eyes)	
	109 subjects (204 eyes)
Male	60
Female	49
Race	
Caucasian	101
Hispanic	2
Asian	3
Black	3
Contact Lens History	
None	85
Soft	107
RGP	12
PMMA	0
Mean Age (Range)	39.8 20- 68

F. Data Analysis and Results

1. Baseline Characteristics

Table 2 contains a summary of the preoperative refractive errors of the entire cohort. Note that the evaluation of the effectiveness (see section 2e. below) concerns the subset of eyes with treatment less than 6.0 diopters spherical equivalent refraction (SER). Baseline characteristics were as follows:

Table 2 Baseline Characteristics All Eyes (N=204)	
Spherical equivalent refraction (SER)	Number (%)
0.00 - 0.99 D	6/204 (2.9)
1.00 - 1.99 D	45/204 (22.1)
2.00 - 2.99 D	44/204 (21.6)
3.00 - 3.99 D	35/204 (17.2)
4.00 - 4.99 D	37/204 (18.1)
5.00 - 5.99 D	16/204 (7.8)
6.00 - 6.99 D	11/204 (5.4)
7.00 - 7.99 D	1/204 (0.5)
8.00 - 8.99 D	3/204 (1.5)
9.00 - ≤15 D	6/204 (2.9)
TOTAL	204 (100.0)
Cylinder	
≤ 0.75D	98 (48.0)
1.00D	25 (12.3)
1.25D	17 (8.3)
1.50D	9 (4.4)
1.75D	9 (4.4)
2.00D	7 (3.4)
2.25D	7 (3.4)
2.50D	6 (2.9)
2.75D	5 (2.5)
3.00D	5 (2.5)
>3.00D	16 (7.8)
TOTAL	204 (100.0)

2. Postoperative Characteristics and Results

a. Patient Accountability

There were 210 eyes enrolled and 204 eyes treated. Accountability for all eyes treated was 86.8% at month 3 and 84.2% at month 6. This surpasses the 80% benchmark. The following cohorts were used for analysis:

- Safety—all eyes (N=204)
- Effectiveness—eyes with treatment of -0.5 to less than -6.0 diopters SER (N=183)
- Stability—subset of all eyes seen at any two consecutive visits, and subset of all eyes seen at all visits (1,3,6 and 12 months)

Table 3
Accountablility

	1 Week	1 Month	3 Months	6 Months	12 Months
Available for Analysis n/N (%)	195/ 204 (95.6%)	192/ 204 (94.1%)	177/ 204 (86.8%)	123/ 204 (60.3%)	92/ 204 (45.1%)
Not yet due for the interval n/N (%)	0/ 204 (0.0%)	0/ 204 (0.0%)	0/ 204 (0.0%)	43/ 204 (21.1%)	45/ 204 (22.1%)
Lost to Follow-up n/N (%)	0/ 204 (0.0%)	0/ 204 (0.0%)	0/ 204 (0.0%)	1/ 204 (0.5%)	10/ 204 (4.9%)
Discontinued n/N (%)	0/ 204 (0.0%)	0/ 204 (0.0%)	0/ 204 (0.0%)	15/ 204 (7.4%)	28/ 204 (13.7%)
Missed Visit n/N (%)	9/ 204 (4.4%)	12/ 204 (5.9%)	27/ 204 (13.2%)	22/ 146 (26.0%)	50/ 131 (67.2%)
% Accountability = Available for Analysis / (Enrolled – Discontinued – Not yet due)	195/ 204 (95.6%)	192/ 204 (94.1%)	177/ 204 (86.8%)	123/ 146 (84.2%)	92/ 131 (70.2%)

N = Total eyes treated

b. Stability of Outcome

In the 3-6 month window, greater than 95% of eyes experienced a change of MRSE not exceeding 1.0 D. Furthermore, the mean of the paired-difference of MRSE progressively decreased over time, and reached a change of less than 0.02 D in the 3-6 months window (Tables 4 to 5). The changes in the 6-12 months window for the entire cohort remained at less than 0.05 D; thus, stability was demonstrated by 6 months postoperative.

Table 4
Stability of Manifest Refraction
(Eyes with two consecutive visits through 12 Months)

Change in Spherical Equivalent	1 and 3 Months n/N (%)	3 and 6 Months n/N (%)	6 and 12 Months n/N (%)
$\leq$ 1.00 D	164/168 (97.6)	103/106 (97.2)	79/79 (100.0)
Mean Difference	-0.13	-0.02	0.03
SD	0.37	0.42	0.38
95% CI (Mean)	(-0.15, -0.11)	(-0.05, 0.01)	(-0.00,0.06)

Table 5 Stability of Manifest Refraction Eyes that had every exam through 12 Months			
Change in Spherical Equivalent Between	1 and 3 Months n/N (%)	3 and 6 Months n/N (%)	6 and 12 Months n/N (%)
$\leq$ 1.00 D	71/72 (98.6)	70/72 (97.2)	72/72 (100.0)
Mean Difference	-0.11	0.02	0.05
SD	0.35	0.37	0.38
95% CI (Mean)	(-0.14, -0.08)	(-0.01, 0.05)	(0.02, 0.08)

c. Effectiveness Outcomes

The analysis of effectiveness was based on the 111 eyes evaluable at the 6 month stability timepoint for the cohort of subjects with preoperative SER of -0.5 to less than -6.0 D. This analysis includes eyes where the cylinder treatment differed from the full preoperative cylinder. In the cohort of all eyes, this difference was > 0.25 D in 11 eyes. Key efficacy outcomes over the course of the study and at the point of stability stratified by diopter of MRSE are presented in tables 6 and 7. At 6 months, 93.5% of eyes had UCVA 20/40 or better and 49.5% of eyes had UCVA 20/20 or better.

Treatments for nearsightedness without astigmatism resulted in undercorrection for some eyes. In the clinical study, for eyes with preoperative SER < 7 D, 24% of eyes without preoperative astigmatism were undercorrected by more than 1.0 D at 6 months.

In the clinical study, the number of eyes treated for 6.0 diopters and greater SER were few, and these eyes had reduced effectiveness and stability outcomes; therefore these data do not support effectiveness of the LSX system for the higher treatment range and are not presented here. No clinical data were presented for any eye with a preoperative cylinder > 4.5 D.

Table 6
Summary of Key Effectiveness Variables Over Time
Eyes with Preop MRSE <6D

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	12 Months n/N (%)
Efficacy Variables				
UCVA 20/20 or better*	89/167 (53.3)	73/150 (48.7)	53/107 (49.5)	43/83 (51.8)
UCVA 20/40 or better*	154/167 (92.2)	136/150 (90.7)	100/107 (93.5)	81/83 (97.6)
MRSE ± 0.50 D	124/175 (70.9)	105/155 (67.7)	72/111 (64.9)	57/84 (67.9)
MRSE ± 1.00 D	164/175 (93.7)	139/155 (89.7)	98/111 (88.3)	73/84 (86.9)
MRSE ± 2.00 D	174/175 (99.4)	153/155 (98.7)	109/111 (98.2)	83/84 (98.8)

*For all eyes minus those intentionally treated for monovision.

Table 7
Summary of Key Efficacy Variables
At 6 months (Stratified by Pre-op MRSE)

	< -1.0 D n/N (%)	-1.0 to -1.99 D n/N (%)	-2.0 to -2.99 D n/N (%)	-3.0 to -3.99 D n/N (%)	-4.0 to -4.99 D N/N (%)	-5.0 to -5.99 D n/N (%)	CUM TOTAL < 6 D n/N (%)
Efficacy Variables							
UCVA 20/20 or better*	3/3 (100)	16/29 (55)	10/20 (50)	8/17 (47)	13/25 (52)	3/13 (23)	53/107 (50)
UCVA 20/40 or better*	3/3 (100)	29/29 (100)	20/20 (100)	15/17 (88)	22/25 (88)	11/13 (85)	100/107 (93)
MRSE ± 0.50 D	1/3 (33)	23/30 (77)	13/20 (65)	11/19 (58)	15/26 (58)	9/13 (69)	72/111 (65)
MRSE ± 1.00 D	3/3 (100)	29/30 (97)	19/20 (95)	16/19 (84)	21/26 (81)	10/13 (77)	98/111 (88)
MRSE ± 2.00 D	3/3 (100)	30/30 (100)	20/20 (100)	18/19 (95)	25/26 (96)	13/13 (100)	109/111 (98)

* For all eyes minus those treated for monovision.

Analysis of the correction of the cylindrical component of the astigmatic eyes is presented in Tables 8 and 9. The Ophthalmic Devices Panel (the Panel), at the January 14, 1997 meeting, assessed outcomes from a myopic astigmatic treatment and provided FDA with recommendations as to acceptable effectiveness rates. The 63.2% mean reduction in absolute cylinder at 6 months is consistent with what the Panel considered acceptable mean reduction in absolute cylinder at the point of stability.

Table 8 Cylinder Correction Efficacy Stratified by Pre-Operative Cylinder (N=88)		
	6 Months	
Pre-Operative Cylinder	Reduction of Absolute Cylinder	
	% Reduction[1] Mean	Ratio[2] Mean
≤ 1.0D	-49.8	0.50
> 1.0 to ≤ 2.0D	-66.3	0.34
> 2.0 to ≤ 3.0D	-78.4	0.22
> 3.0 to ≤ 4.0D	-94.8	0.05
> 4.0 to ≤ 4.5D	-86.5	0.14
Total	-63.2	0.37

1. [(Post-op cylinder - Pre-op cylinder) / Pre-op cylinder] x 100
2. Post-op cylinder / Pre-op cylinder

Looking at intended versus achieved vector magnitude cylinder, the Intended Refractive Correction ("IRC") had a mean of 1.50 D with a median of 1.25 D (range –1.50 to 4.50 D). The Surgically Induced Refractive Correction ("SIRC") had a mean of 1.41 D with a median of 1.00 D (range –1.50 to 5.50 D). The vector magnitude ratio (SIRC/IRC) was 0.77 at 6 months. The Panel has found 0.82 acceptable for correction efficacy (SIRC/IRC) at stability.

Table 9 Cylinder Correction Efficacy Stratified by Pre-Operative Cylinder (N=90)	
	6 Months
Pre-Operative Cylinder	Achieved vs Intended Vector Magnitude Ratio (Achieved/Intended) Mean
≤ 1.0D	0.62
> 1.0 to ≤ 2.0D	0.82
> 2.0 to ≤ 3.0D	0.98
> 3.0 to ≤ 4.0D	1.03
> 4.0 to ≤ 4.5D	1.04
Total	0.77

d. Key Safety Results

The analysis of safety was based on the cohort of all 204 eyes treated in the clinical study. Safety was evaluated based on maintenance of BSCVA, surgical induction of additional refractive cylinder, and adverse events and complications. Table 10 presents a summary of key safety variables for all eyes treated at the 1, 3 and 6 month visits. The proportion of eyes at 1 month with a BSCVA worse than 20/25 if 20/20 or better preoperatively was 2.1%. No eyes were reported to have a BSCVA worse than 20/40 or a loss of >2 lines of BSCVA at any visit.

Table 10

Summary of Key Safety Variables Over Time
(all eyes treated)

Safety Variable	1 Month N= 192 n (%)	3 Months N= 174 n (%)	6 Months N=123 n (%)
Loss of >2 lines BSCVA.	0 (0.0)	0 (0.0)	0 (0.0)
Loss of ≥ 2 Lines BSCVA	4 (2.1)	1 (0.6)	1 (0.8)
BSCVA worse than 20/40.	0 (0.0)	0 (0.0)	0 (0.0)
Increase of > 2D cylinder#	0/52 (0.0)	0/44 (0.0)	0/33 (0.0)
BSCVA worse than 20/25 if 20/20 or better preoperatively	4 (2.1)	0 (0.0)	0 (0.0)

Tables 11 and 12 summarize adverse events and complications experienced following LASIK treatment of myopia with and without astigmatism for all eyes. The benchmark for each adverse event (Table 11) is a rate of less than 1% per event. There were no adverse events at a rate over 1%. With regard to complications, 2.8% had epithelial ingrowth. Overall, the device was deemed reasonably safe.

Table 11
Adverse Events Summary Table

Adverse Events	1 Month		3 Months		6 Months	
	n/N	%	n/N	%	n/N	%
Macerated Flap	0/202	0.0	0/204	0.0	0/143	0.0
Perforated Cornea	0/202	0.0	0/204	0.0	0/143	0.0
Incorrect manifest entered into laser	0/202	0.0	0/204	0.0	0/143	0.0
Corneal Infiltrate, ulcer or perforations	0/202	0.0	0/204	0.0	0/143	0.0
Epithelial Defect involving keratectomy	0/202	0.0	0/204	0.0	0/143	0.0
Corneal edema	0/202	0.0	0/204	0.0	0/143	0.0
Epithelium in interface w/loss > 2 lines BSCVA	0/202	0.0	0/204	0.0	0/143	0.0
Intraocular Infection	0/202	0.0	0/204	0.0	0/143	0.0
Uncontrolled IOP with increase of > 10 mm Hg above baseline and any reading above 25 mmHg	0/202	0.0	0/204	0.0	1/143	0.7
Lost ,misplaced, misaligned, or dislocated flap	0/202	0.0	0/204	0.0	0/143	0.0
Melting of the flap	0/202	0.0	0/204	0.0	0/143	0.0
Flap Necrosis	0/202	0.0	0/204	0.0	0/143	0.0
Decrease of > 10 letters BSCVA at 6 months not due to irregular astigmatism	0/202	0.0	0/204	0.0	0/143	0.0
Loss of > 2 lines BSCVA at 6 months	0/202	0.0	0/204	0.0	0/143	0.0
Perforation of cornea into anterior chamber	0/202	0.0	0/204	0.0	0/143	0.0
Retinal detachment	0/202	0.0	0/204	0.0	0/143	0.0
Retinal vascular accidents	0/202	0.0	0/204	0.0	0/143	0.0

Table 12
Complications Summary Table

Complications	1 Month		3 Months		6 Months	
	n/N	%	**n/N**	**%**	**n/N**	**%**
Keratectomy Irregular	0/202	0.0	0/204	0.0	0/143	0.0
Epithelial Defect	0/202	0.0	0/204	0.0	0/143	0.0
Cap Striae	1/202	0.5	0/204	0.0	0/143	0.0
Free Cap	0/202	0.0	0/204	0.0	0/143	0.0
Decentered Ablation	0/202	0.0	0/204	0.0	0/143	0.0
Interrupted Treatment	0/202	0.0	0/204	0.0	0/143	0.0
Persistent Subject Movement	0/202	0.0	0/204	0.0	0/143	0.0
Epithelierum in the Interface/Ingrowth	9/202	4.5	5/204	2.5	4/143	2.8
Corneal Erosion	0/202	0.0	2/204	1.0	0/143	0.0
Foreign Body Sensation	0/202	0.0	0/204	0.0	0/143	0.0
Pain	0/202	0.0	0/204	0.0	0/143	0.0
Ghosts/Double Images	0/202	0.0	2/204	1.0	0/143	0.0
Flap not the Size Intended	1/202	0.5	0/204	0.0	0/143	0.0
Corneal Edema	4/202	2.0	0/204	0.0	0/143	0.0
Peripheral Epithelial Defect	1/202	0.5	0/204	0.0	0/143	0.0
Flap Tear/Defect	0/202	0.0	0/204	0.0	0/143	0.0
Lamellar Keratitis (SOS/DLK)	0/202	0.0	0/204	0.0	0/143	0.0
Debris in the Interface	0/202	0.0	0/204	0.0	0/143	0.0

e. Retreatment

Fourteen eyes were retreated with the study laser due to undercorrection and/or regression. Table 13 contains the outcomes of the retreated eyes. There were insufficient data to form definitive conclusions regarding the safety and effectiveness of retreatment with this device.

Table 13
Summary of Key Safety and Efficacy Variables
Eyes Retreated – Last Treatment

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Efficacy Variables			
UCVA 20/20 or better*	13/14 (92.9)	8/10 (80.0)	---
UCVA 20/40 or better*	14/14 (100)	10/10 (100)	---
MRSE ± 0.50 D	11/13 (84.6)	10/11 (90.9)	---
MRSE ± 1.00 D	13/13 (100)	10/11 (90.9)	---
MRSE ± 2.00 D	13/13 (100)	11/11 (100)	---
Safety Variables			
Loss of ≥ 2 lines BSCVA	0/13 (0.0)	0/11 (0.0)	---
BSCVA worse than 20/40	0/13 (0.0)	0/11 (0.0)	---
Increase of > 2 D cylinder#	0/3 (0.0)	0.3 (0.0)	---
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/13 (0.0)	0/11 (0.0)	---

*For all eyes minus those intentionally treated for monovision.
For eyes treated for spherical correction only.

f. Factors Associated with Outcomes

Table 14 displays results of the testing for association between several baseline characteristics and 6 month outcomes. A significant association between patient age and the proportion of eyes with UCVA 20/20 or better was found (p=0.0022, Fisher's Exact test). Similarly, patient age was associated with the proportion of eyes within 1 D of intended MRSE (p=0.0364). In both cases, patients with ages at the median (39.7 years) or younger had significantly better visual acuity and refractive outcomes at 6 months, than patients above the median age. No other significant associations between patient gender, race or contact lens wear were found.

Table 14
Association Between Pre-Operative factors and 6 Month Outcomes[1]

Pre-Operative Dichotomous Factor	UCVA 20/20 p-Value	MRSE Within 1 D of Intended p-Value
Gender (M/F)	0.8599	0.2051
Age (≤ 39.7 or > 39.7)[2]	0.0022	0.0364
Race (White or Non-White)	1.0000	1.0000
Contact Lens Wear (Yes/No)	0.1101	0.2054

1. Association between preoperative factor and outcome determined by results of Fisher's Exact test (2x2 table).
2. Median age

g. Patient Symptoms

In the clinical study, before and 6 months after surgery patients were asked to rate a series of subjective events. The percentage of patients that rated each condition as "often" or "always" preoperatively and at 6 months is listed below in Table 15.

Table 15
Patient Events at Preop and 6 months

PATIENT SYMPTOMS	Eyes Without astigmatism		Eyes With astigmatism	
	PREOP n/N (%)	**6 MO** n/N (%)	**PREOP** n/N (%)	**6 MO** n/N (%)
Foreign Body Sensation	0/52 (0.0)	2/24 (8.3)	3/144 (2.1)	5/55 (9.1)
Burning Feeling	1/52 (1.9)	0/24 (0.0)	5/144 (3.5)	3/55 (5.5)
Watery Eyes	5/52 (9.6)	0/24 (0.0)	9/144 (6.3)	3/55 (5.5)
Halos/Starbursts	5/52 (9.6)	3/24 (12.5)	18/144 (12.5)	2/55 (3.6)
Double Vision	0/52 (0.0)	0/23 (0.0)	1/144 (0.7)	0/54 (0.0)
Clarity Changes	5/52 (9.6)	7/24 (29.2)	9/144 (6.3)	5/55 (9.1)
Night Vision Problems While Driving	12/52 (23.1)	9/24 (37.5)	40/144 (27.8)	14/55 (25.5)

h. Patient Satisfaction

Subjects were asked to rate their satisfaction with the surgery on a scale of 1-10, 1 "being very disappointed" and 10 "being very satisfied". The results of the questionnaire are listed below:

Table 16
Patient Satisfaction at 6 Months

	N	Mean	Median	Std	Range
Patient Satisfaction (1-10)	77	8.7	10	2	3.0 - 10.0

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The data in this application support reasonable assurance of the safety and effectiveness of this device when used in accordance with the approved indications for use.

XII. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515 (c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. FDA DECISION

CDRH issued a major deficiency letter to LaserSight Technologies on March 15, 2001. In amendments received on April 19, May 11, July 10, July 12, August 1, and September 4, 2001 LaserSight submitted the required changes, clarification and information. The applicant addressed all the labeling concerns raised by FDA. CDRH issued an approval order on September 28, 2001.

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See Device Labeling.

Hazards to health from use of the device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.