



## Summary of FDA Nearsighted Surgical Results Data for all Conventional LASIK Approved Excimer Laser Systems

Document Source: [www.fda.gov/cdrh/lasik/lasers.htm](http://www.fda.gov/cdrh/lasik/lasers.htm)

	Accuracy Data			Safety Data
	Vision without Glasses $\geq$ 20/20 at 6 mo post-op	Vision without Glasses $\geq$ 20/40 at 6 mo post-op	Prescription w/in $\pm$ 0.50 Step of Intended	Loss of $\geq$ 2 Lines Best Possible Vision with Glasses
Autonomous Ladarvision*	56.9%	93.7%	70.6%	1.2%
B+L Technolas 217**	87.3%	99.7%	86.7%	0.3%
LaserSight	53.1%	85.4%	58.5%	0.9%
Nidek	47.4%	84.4%	60.3%	0.9%
Summit	46.9%	92.1%	67.8%	1.4%
VISX	54.1%	95.4%	78.0%	0.4%

\* Data obtained using 4000 hertz Eye Tracking System

\*\* Data obtained prior to introduction of Eye Tracking System that is currently used on our "Z" version of the laser

Data for Post Operative Uncorrected Visual Acuities taken from FDA Approval Letters sent to laser manufacturers  
Refers to non-retreated eyes only

### ---- Explanation Of Terms ----

**Vision without Glasses  $\geq$  20/20 at 6 mo post-op:** This is the percentage of eyes which achieved 20/20 or better vision without glasses or contact lenses after LASIK. This is an indicator of the accuracy of the laser.

**Vision without Glasses  $\geq$  20/40 at 6 mo post-op:** This is the percentage of eyes which achieved 20/40 (legal driving vision) or better vision without glasses or contact lenses after LASIK. This is another indicator of the accuracy of the laser.

**Prescription w/in  $\pm$ 0.50 Step of Intended:** This is the percentage of eyes after treatment that were within  $\frac{1}{2}$  step of power from where the surgeon intended them to be refractively. Not all treatments are aimed for zero power depending on the patients needs and lifestyle. This is another indicator of the accuracy of the lasers.

**Loss of  $\geq$  2 Lines Best Possible Vision with Glasses:** This is the percentage of eyes which lost the ability to see 2 or more lines on the eye chart after treatment as compared to with glasses or contact lenses before treatment. Two lines on the eye chart is the difference between 20/20 and 20/40 or 20/15 and 20/25. This is an indicator of the safety of laser vision correction. None of the patients studied lost significant amounts of vision and there was no blindness as the result of the treatments in any of these large studies.