

Zyoptix® Technolas® Risks and Benefits

- a. Approval of the premarket approval application supplement is for the TECHNOLAS 217z Zyoptix System for Personalized Vision Correction to perform wavefront-guided LASIK treatments in patients 21 years of age or older for the reduction or elimination of myopia up to -7.00 D sphere with up to -3.00 D of astigmatism and MRSE \leq 7.50 D at the spectacle plane; and in patients with documented stability of refraction for the 12 months prior to the date of the preoperative examination, as demonstrated by a change of less than or equal to 0.50 D.
- b. Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries.
- c. Approval of the application is based on a clinical trial of 340 eyes (117 spherical eyes and 223 spherocylindrical eyes). All treated eyes were available for analysis of safety at 3 months, and all eyes were followed for 6 months. Accountability at 3 and 6 months was 100.0%. All 340 eyes were evaluated for effectiveness with 100.0% accountability at both 3 and 6 months.
- d. The analysis of data from 340 total eyes treated and based on refractive data at 6 month follow-up examination, found that 99.4% (338/340) were corrected to 20/40 or better and 91.5% (311/340) were corrected to 20/20 or better visual acuity without spectacles or contact lenses.
- e. The study showed that at the 6-month stability timepoint: there was a loss of \geq 2 lines of best-corrected vision that can be obtained with spectacles in 1/223 astigmatic myopia eyes and in 1/117 spherical myopia eyes; there were no eyes with astigmatic or spherical myopia with best spectacle-corrected visual acuity (BSCVA) worse than 20/25 (if 20/20 or better preoperatively). During the course of study, no eye lost $>$ 2 lines of BSCVA and no eye had a BSCVA worse than 20/40.
- f. The clinical trials showed that the following adverse events occurred in at least 1% of the 340 eyes at any interval up to 6 months post-treatment: debris in the interface (5.3% at 1 month; 2.4% at 3 months; and 1.2% at 6 months). The following subjective patient adverse events rated “significantly worse” occurred in at least 1% of 340 eyes in the effectiveness cohort at 6 months post-treatment: Fluctuation of vision (4.2%); blurring of vision (3.8%); glare (3.2%); halos (2.6%); dryness and double vision (2.4% each); headache, redness, and night driving difficulty (1.2% each).
- g. The safety and effectiveness of wavefront-guided LASIK surgery has ONLY been established with an optical zone size between 6.0 mm and 7.0 mm with a constant blend zone of .875 mm.
- h. Long-term risks of wavefront-guided LASIK for myopia and myopic astigmatism beyond 6 months have not been studied.
- i. The safety and effectiveness of the Bausch & Lomb TECHNOLAS 217z Zyoptix System have NOT been established for wavefront-guided surgery in patients whose wavefront-measured pupil size is less than 6.00 mm or greater than 7.00 mm; for treatments greater than -7.00 D spherical myopia, or greater than -3.00 D cylinder, or greater than -7.50 D MRSE.
- j. Although the Zywave® Wavefront System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher-order aberrations through fifth order, in the clinical study for this PMA, the average higher-order aberration did not decrease after Zyoptix Personalized Vision Correction.