

PMA P970043/S010

CustomCornea™ Myopic LASIK with the LADARVision™4000 System

1. Proposed indication for use is :
 - ?? in Wavefront-Guided CustomCornea[?] Laser In-Situ Keratomileusis (LASIK) correction for the reduction or elimination of myopia up to -7D with less than – 0.50D of astigmatism at the spectacle plane;
 - ?? in subjects with documented stability of refraction for the prior 12 months, as demonstrated by a change of less than or equal to 0.50D; and,
 - ?? in subjects who are 21 years of age or older.
2. Device Characteristics
 - ?? An argon fluoride excimer laser previously approved for LASIK
 - ?? Modification is in the method by which the planned ablation pattern is determined, and not the ablation technology . The pulse energy, firing rate, fluence distribution at the treatment plane, and eye tracking hardware and software are the same for conventional and CustomCornea™ treatment modalities. In the previously approved version (conventional LADARVision™), the ablation pattern was based upon manually entered manifest subjective refraction data (sphere and cylinder). The CustomCornea™ ablative shaping algorithm utilizes information that is obtained from the wavefront measurement device. Wavefront sensing provides a detailed refractive map (including sphere, cylinder and “higher order” aberrations) unique for each eye. This information is electronically transferred to treatment laser. Ablation profile is calculated directly from wavefront data.
3. Safety Cohort (n = 426)
 - ?? Sphere up to -7.00D
 - ?? Astigmatism up to -4.00D
4. Primary Effectiveness Cohort (n = 139)
 - ?? Sphere up to -7.00D
 - ?? Astigmatism less than -0.50D
 - ?? Sponsor has decided to limit the requested approval range to the spherical myopia cohort only. This decision was based on the sponsor’s analysis of efficacy outcomes of astigmatic treatment. Sponsor is working to improve trends in myopic astigmatic eyes prior to seeking approval of myopic astigmatism.
5. Accountability, stability, safety and efficacy outcomes are all acceptable. No major clinical issues. Vision Science related issues remain.