

Questions for Panel Discussion

P870024/S043

1. Do the data reported for the two different generic lens materials evaluated during the study raise any questions of safety and effectiveness?
2. Do the data reported for the two reverse geometry lens designs evaluated during the study raise any questions of safety and effectiveness?
3. Is the length of follow-up sufficient to demonstrate the stability of the intended myopic reduction with the prescribed maintenance regimen?
4. What are the panel's recommendations for the proposed product labeling (e.g., warnings, precautions, terminology to describe the procedure)?
5. What are the panel's recommendations regarding post-approval follow-up of the study subjects or a post-approval study of corneal warpage affects over time?
6. Do the data presented in this PMA provide reasonable assurance of safety and effectiveness for the stated indications?