

**Voting Questions**  
**Ophthalmic Devices Panel of the Medical Devices Advisory Committee**

The applicant has proposed the following Indication for Use:

**The VisAbility™ Micro Insert is indicated for bilateral scleral implantation to improve unaided near vision in phakic, presbyopic patients between the ages of 45 and 60 years of age, who have a manifest spherical equivalent between -0.75 D and +0.50 D with less than or equal to 1.00 D of refractive cylinder in both eyes, and require a minimum near correction of at least +1.25 D reading add.**

The following questions relate to the approvability of the VisAbility™ Micro Insert System.

Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:

**Is there reasonable assurance that the VisAbility™ Micro Insert System is safe for use in patients who meet the criteria specified in the proposed indication?**

Voting Question 2:

**Is there reasonable assurance that the VisAbility™ Micro Insert System is effective for use in the patients who meet the criteria specified in the proposed indication?**

Voting Question 3:

**Do the benefits of the VisAbility™ Micro Insert System outweigh the risk for use in the patients who meet the criteria specified in the proposed indication?**