

## OPHTHALMIC DEVICES PANEL

### MEMBERSHIP

A roster of members is attached.

### MEETINGS

The Panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of those meetings were October 3, 2003, February 5-6, 2004, and March 5, 2004.

The meeting on February 5-6, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

### ACCOMPLISHMENTS

#### **At the October 3, 2003 meeting:**

In the open session, a PMA supplement for the STAAR Myopic Implantable Contact Lens (ICL™) was recommended for approval with conditions. The device, a phakic intraocular lens, is indicated for the correction of moderate to high myopia with placement in the posterior chamber of the phakic eye. The Panel's conditions included changes in the indications for use, additions to both patient and physician labeling and consideration of post-market studies.

#### **At the February 5-6, 2004 meeting:**

In the open session, during the first day, a PMA for the ARTISAN™ Myopia Phakic Intraocular lens was recommended for approval with conditions. The device is indicated for the reduction or elimination of myopia in adults. The conditions included:

- Agency should determine the age and minimum corneal endothelial cell count allowable for implantation of the lens.
- The sponsor should reanalyze the existing data for pigment dispersion and elevated intraocular pressure in the minority subset of the cohort.
- Perform a 2-3 year post-market study to further evaluate the incidence of retinal detachments, lens explants, and cataract formation.
- Strengthen the physician and patient labeling with various recommendations including clarification or elimination of confusing terms, and additional warnings and precautions.

Agency Action: On September 10, 2004, FDA issued an approval order for the device.

On the second day, a PMA for the Viewpoint™ Conductive Keratoplasty (CK) System was recommended for approval with conditions. This radiofrequency electrosurgical corneal shaping device is indicated for the temporary spherical treatment in the non-dominant eye of presbyopic emmetropes or presbyopic hyperopes. One condition was slightly restricting the indications statement to reflect an intended range of refractive correction to 1.00 to 2.25 diopters of effect.

Ophthalmic Devices Panel (*continued*)

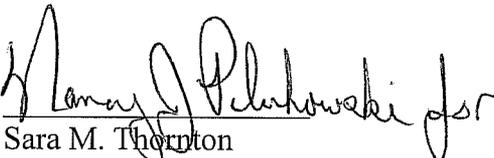
The other condition strengthened the physician and patient labeling by adding information: (a) safety and effectiveness of retreatments have not been determined; (b) nystagmus should be a contraindication; (c) a table that defines the frequency of induced astigmatism and the effect on near and distance vision; and (d) a graph of the total effect of regression over time to focus attention on the temporary nature of the procedure's vision improvement.

**Closed Committee Deliberations:** On February 6, 2004, the meeting was closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting was closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

**At the March 5, 2004 meeting:**

The Panel discussed issues related to the appropriate clinical trial design for the evaluation of multifocal or accommodative intraocular lenses (IOLs) in a cohort of subjects who have undergone clear lens extraction to correct presbyopia. Clear lens extraction is an intraocular surgical procedure in which the non-cataractous crystalline lens is removed and replaced with a multifocal or accommodative lens for refractive correction. There was no vote taken nor consensus requested of the Panel. The purpose of the meeting was to assist FDA in working with industry to design clinical trial protocols that would establish the reasonable safety and effectiveness of clear lens extraction with implantation of a multifocal or accommodative IOL.

September 30, 2004  
Date

  
Sara M. Thornton  
Executive Secretary

# Ophthalmic Devices Panel Roster

## ***Chairperson***

### **Jayne S. Weiss, M.D.**

Expertise: Ophthalmological Surgery  
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