

APPENDIX 1

**CROSS REFERENCE OF INFORMATION IN
EXECUTIVE SUMMARY TO ISSUES RAISED AT
JULY 2006 PANEL REVIEW OF P050034**

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ISSUES RAISED AT JULY 2006 OPHTHALMIC DEVICES ADVISORY PANEL
REVIEW OF P050034

This attachment provides a guide to the location in this Executive Summary of data, analyses, and information responsive to issues raised at the July 2006 meeting of the Ophthalmic Devices Advisory Panel, as follows:

1. Provide endothelial cell morphometric data; the percent of hexagonal cell (% Hex) and the variability in size of cell, coefficient of variation (CV) to assess the stability of the cornea endothelium in subjects implanted with the IMT. Determine the point of stabilization and reanalyze the endothelial cell density to determine acute and chronic rates of cornea endothelial cell loss. Longer-term data may be required for the analysis.

This issue is addressed beginning on page 70 of the Executive Summary.

2. Preliminary IMT to cornea endothelial surface clearance was provided on seven patients. Provide additional clearance data to evaluate the impact of anterior chamber depth on the safety of subjects implanted with the IMT.

This issue is addressed beginning on page 107 of the Executive Summary.

3. The contribution of cataract removal to the efficacy of IMT implanted eyes was identified as an issue regarding device efficacy. Analyze visual acuity improvement based cataract surgery alone.

These issues are addressed beginning on page 26, as part of the presentation of data on best corrected visual acuity.

4. Information was not presented or discussed on the 11 subjects not successfully implanted with the IMT, the 12 subjects that had the IMT removed and 13 subjects that missed the 24 month visit. Provide available information.

Detailed information on the 11 subjects not successfully implanted with the IMT is provided in a set of data tables found in Attachment 3. Also in Attachment 3 is a set of data tables on the 13 subjects who did not return for the 24 month follow-up visit; this information begins on page 8.

Information on the 12 subjects who had the IMT removed during the study is provided in the Executive Summary, Section 6.4, Ocular Complications and Adverse Events, beginning on page 83.

5. Provide recommended procedures for examination of the posterior segment in subject implanted with the IMT.

Detailed information on performing posterior segment examination in eyes with an IMT in place may be found in the Physician Training provided in Attachment 15 of this submission.