

## Summary

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The test article, HARD CLAD OPTICAL FIBER, Lot: B042409A-1, was evaluated for systemic toxicity in mice in accordance with the International Organization for Standardization 10993-11: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity. The test article was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five mice. Similarly, a separate group of five mice was dosed with each corresponding blank vehicle. The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection.

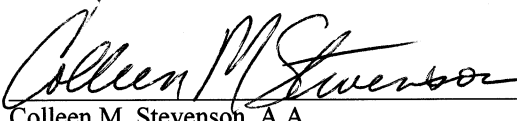
Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts. The test article extracts met the requirements of the study.

### Study and Supervisory

Personnel:

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6.3.09  
Date Completed

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