

Confidential
TCLVI_E05

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Lab No. 05T_36386_11
P.O. No. IC050605
Test Facility: NAMSA
6750 Wales Road
Northwood, OH 43619

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, *IN VIVO*
USP PLASTIC CLASS VI

Test Article: Optical Fiber with hard plastic cladding and ETFE buffer coating
ID No. BH-0032

USP Systemic Toxicity Study in the Mouse: The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit: The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit: The macroscopic reaction of the test article, implanted in rabbit muscle for 5 days, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 60 cm²:20 ml and extracted at 70°C for 24 hour. The test article extracts met the requirements of a USP Plastic Class VI.

and Date Completed 6-17-09

Approved By

Cherise M. McCoy
Cherise M. McCoy, B.S.
Technical Reviewer