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Confidential
TCLVI-E05

Lab No. 98T 14203 00
P.O. No. 16807

FIBERGUIDE INDUSTRIES, INC.
1 BAY STREET

ID NO. Lot: CA-0203/
Glass Lot #86003510/
Silicone Lot
#ET028411 / Nylon
Lot #UD30F07

STIRLING, NJ 07980
ATTN: IRFAN CAMLIBEL

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, *IN VIVO*

CLASSIFICATION VI

Test Article: SFS400/440/540/640SSN Superguide G Fiber with Strippable Silicone Buffer and Nylon Jacket

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 cottonseed 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 cottonseed 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 hours. The test article extracts met the requirements of a USP Plastic Class VI.

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Date Completed

24 November 1998

Approved By

J. Matthew Buchanan, BS, MS