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Confidential TCLAS_VI5

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CERTIFICATE OF COMPLIANCE USP BIOLOGICAL REACTIVITY TESTS, IN VIVO

USP PLASTIC CLASS VI

Test Article:

Polypropylene Pellets, YUNGSOX 5018

ID No.

Batch: PH9401

<u>USP Systemic Toxicity Study in the Mouse</u>: 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.

<u>USP Intracutaneous Toxicity Study in the Rabbit</u>: 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.

<u>USP Muscle Implantation Study in the Rabbit</u>: The macroscopic reaction of the test article, implanted in rabbit muscle for 6 days, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 4 g:20 ml and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

nee Date Completed 2.14.06

Approved By

By July A 7
John A. Firneno

Manager, In Vitro / Toxicology