

K955444

510(k) Summary  
Abbott AxSYM Procainamide  
Summary of Safety and Effectiveness Information Supporting a  
Substantial Equivalent Determination

APR - 2 1996

The following information as presented in the Premarket Notification 510(k) for AxSYM Procainamide constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between the AxSYM Procainamide assay and the TDx/TDxFLx Procainamide assay. Both assays are automated fluorescence polarization immunoassays (FPIA). The intended use of both assays is for the quantitative determination of procainamide in human serum or plasma (sodium heparin, tripotassium EDTA, potassium oxalate, and sodium citrate). Both assays are calibrated with Abbott calibrators. Abbott controls are assayed controls used for verification of the accuracy and precision of the AxSYM system. Correlation studies indicated the following results:

Slope: 0.98  
Y-Intercept: 0.1  
Correlation Coefficient: 0.989  
Std. Error of the Y estimate: 0.056  
Number: 205

The AxSYM Procainamide standard calibrators and controls are to be used with the AxSYM Procainamide reagents. The calibrators and controls are prepared gravimetrically using purified material obtained from commercial sources. The calibrators and controls are verified using protocols involving multiple instrument testing. AxSYM Procainamide reagent, calibrator and control expiration dates are based on real time stability testing.

Prepared and Submitted :

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