K955851

510(k) Summary
Abbott AxSYM® Vancomycin II

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Summary of Safety and Effectiveness Information Supporting a Substantial Equivalent Determination

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

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

Slope: 1.03
Y-Intercept: -1.08
Correlation Coefficient: 0.99
Std. Error of the Y estimate: 2.74
Number: 217

The AxSYM Vancomycin II standard calibrators and controls are to be used with the AxSYM Vancomycin II 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 Vancomycin II reagent, calibrator and control expiration dates are based on real time stability testing.

Prepared and Submitted :

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