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510(k) Summary
Abbott AxSYM® B12

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Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the Premarket Notification for AxSYM® B12 constitutes data supporting a substantially equivalent determination.

AxSYM B12 is a microparticle enzyme intrinsic factor assay for the quantitative determination of vitamin B_{12} in human serum or plasma. AxSYM B12 is calibrated with Abbott B12 calibrators. Abbott B12 controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM System.

Substantial equivalence has been demonstrated between the Abbott AxSYM B12 assay and the Abbott IMx® B12 assay. The intended use of both assays is for the quantitative determination of vitamin B_{12}. AxSYM B12 can be performed with human serum or plasma (tripotassium EDTA and potassium oxalate). However, IMx B12 can be performed on human serum and plasma (EDTA only). A correlation analysis between these two assays, using 337 specimens, yielded a correlation coefficient of 0.975, slope of 1.00, standard error of y estimate of 67.281, and y-intercept of -12.371 pg/mL. Both assays have a dynamic range of 60 to 2,000 pg/mL.

In conclusion, these data demonstrate that Abbott AxSYM B12 is safe and effective, and is substantially equivalent to Abbott IMx B12.

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