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510(K) SUMMARY
ABBOTT AxSYM PROGESTERONE

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A SUBSTANTIALLY EQUIVALENT DETERMINATION

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

AxSYM Progesterone is a microparticle enzyme immunoassay for the quantitative determination of progesterone in human serum and plasma (heparin or EDTA). AxSYM Progesterone is calibrated with Abbott calibrators and Abbott controls are used for verification of the calibration and to monitor the performance of the Abbott AxSYM System.

Substantial equivalence has been demonstrated between the Abbott AxSYM Progesterone assay and the Diagnostics Products Corporation Coat-A-Count® Progesterone assay. The intended use of both assays is for the quantitative determination of progesterone in human serum or plasma . A correlation analysis between these two assays, using 209 specimens, yielded a correlation coefficient of 0.96, slope of 0.86, standard error of Y-estimate of 2.29 and Y-axis intercept of 0.77 ng/mL. Both assays have a dynamic range of 0 - 40 ng/mL progesterone.

In conclusion, these data demonstrate that the AxSYM Progesterone assay is as safe and effective and is substantially equivalent to the Diagnostics Products Corporation Coat-A-Count Progesterone assay.

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