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SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial equivalence has been demonstrated between the INNOFLUOR™ Quinidine Assay System (Modified) the INNOFLUOR™ Quinidine Reagent Set (Existing) and the Abbott Quinidine Assay.

The technological characteristics, performance and intended use of the INNOFLUOR™ Quinidine Assay System (Modified) are substantially equivalent to the INNOFLUOR™ Quinidine Reagent Set (Existing) and the Abbott Quinidine Assay.

Quinidine concentrations measured by the INNOFLUOR™ QUINIDINE Assay System (Modified), (INNOFLUOR™), on the Abbott TDx® analyzer were compared with those measured by the Abbott Quinidine Assay, (Abbott), on 49 serum patient samples. Comparison of the patient sample results by linear regression analysis resulted in the regression equation: (INNOFLUOR™) = 0.958 x (Abbott) - 0.077, with a correlation coefficient of 0.986.