DADE

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DADE INTERNATIONAL

Chemistry Systems
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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Vancomycin FLEX™ Reagent Cartridge

Summary of Safety and Effectiveness

The VANC FLEX™ reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure vancomycin, an antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

The VANC method is based on a Particle Enhanced Turbidimetric Inhibition Immunoassay (PETINIA) technique which uses a latex particle-vancomycin conjugate and vancomycin-specific monoclonal antibody.

The VANC FLEX™ reagent cartridge is substantially equivalent to the aca® analytical test pack, which was cleared by the FDA through the 510(k) process. Both tests used prepackaged reagents for the determination of vancomycin in human serum and plasma.

Two hundred thirty-one samples were tested with the VANC FLEX™ reagent cartridge on the Dimension® system and the aca® VANC test pack on the aca® discrete clinical analyzer, with the following results:

slope = 0.95
intercept = -0.33
correlation coefficient = 0.987
range of samples = 0.1 - 49.8 µg/mL

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Date