DADE

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DADE INTERNATIONAL

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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

Carbamazepine FLEX™ Reagent Cartridge

Summary of Safety and Effectiveness

The CRBM FLEX™ reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure carbamazepine, an anti-convulsant drug, in plasma or serum. Measurements obtained by this device are used in the diagnosis and treatment of carbamazepine overdose and in monitoring levels of carbamazepine to ensure appropriate therapy.

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

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

Eighty-two samples were tested with the CRBM FLEX™ reagent cartridge on the Dimension® system and the aca® CRBAM test pack on the aca® discrete clinical analyzer, with the following results:

slope = 0.99
intercept = 0.06
correlation coefficient = 0.979
range of samples = 0-18.6 µg/mL

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Date