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

Gentamicin FLEX™ Reagent Cartridge

Summary of Safety and Effectiveness

The GENT FLEX™ reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure gentamicin, an aminoglycoside antibiotic drug, in human specimens. Measurements obtained by this assay are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.

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

The GENT FLEX™ reagent cartridge is substantially equivalent to the Abbott AxSYM® Gentamicin assay, which was cleared by the FDA through the 510(k) process. Both tests use liquid reagents in an automated system for the determination of gentamicin in human serum or plasma.

One hundred ninety-seven samples were tested with the GENT FLEX™ reagent cartridge on the Dimension® system and the Abbott Gentamicin assay on the Abbott AxSYM®, with the following results:

slope = 1.02
intercept = -0.15
correlation coefficient = 0.987
range of samples = 0.1-10.6 µg/mL

AxSYM® is a registered trademark of Abbott Laboratories, Abbott Park, IL 60064.

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Date