DADE

K962818

DADE INTERNATIONAL

Chemistry Systems
P.O. Box 6101
Newark, DE 19714

SEP 13 1996

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

Tobramycin FLEX™ Reagent Cartridge

Summary of Safety and Effectiveness

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

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

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

One hundred forty-one samples were tested with the TOBR FLEX™ reagent cartridge on the Dimension® system and the aca® TOBRA test pack on the aca® discrete clinical analyzer, with the following results:

slope = 0.99
intercept = 0.10
correlation coefficient = 0.989
range of samples = 0-12 µg/mL

Carolyn K. George

Carolyn K. George
Regulatory Affairs and
Compliance Manager

September 4, 1996
Date