# 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

**Acetaminophen FLEX™ Reagent Cartridge**

Summary of Safety and Effectiveness

The ACTM FLEX™ reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure the drug acetaminophen in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

The ACTM method is based on the enzymatic hydrolysis of acetaminophen producing acetate and p-aminophenol. The amount of p-aminophenol is measured colorimetrically and is proportional to the acetaminophen concentration.

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

One hundred fifty-four serum or plasma samples were tested with the ACTM FLEX™ reagent cartridge on the Dimension® system and the aca® ACTMN analytical test pack on the aca® discrete clinical analyzer, with the following results:

slope = 1.04
intercept = -3.27
correlation coefficient = 0.998
range of samples = 10.2 - 295.0 µg/mL

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Date