

K964715 APR 25 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

PARAMAX® SALICYLATE REAGENT

Dade International, Inc.
2173 NW 99 Avenue
Miami, Fl 33172

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Trade or Proprietary Name: Paramax® Salicylate Reagent

Common or Usual Name: Salicylate Reagent

Classification Name: Colormetric Salicylate, 21 CFR 862.3830

Registration Number: **1025506**
Dade International, Inc.
2173 NW 99 Avenue
Miami, Fl 33172

1017272
Dade International, inc.
1851 Delaware Parkway
Miami, Fl 33125

2649587
Dade International Puerto Rico
Building 187-67
Road 115
KM 22.6
Aguada, P.R. 00602

The Paramax® Salicylate Reagent is substantially equivalent to its predecessor, which was cleared to market on K771805. The proposed and the predicate device are intended for use as quantitative determination of salicylate in plasma and serum.

The Paramax® Salicylate Reagent and DuPont aca Salicylate Reagent are based on colormetric methodology.

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PARAMAX® SALICYLATE REAGENT (con't)**

The technological characteristics of the predicate device are similar to those previously described for the proposed device.

The correlation between the Paramax® Salicylate Reagent and Dupont aca Salicylate Reagent was demonstrated by testing 49 samples on a Paramax® and a DuPont aca System. The correlation coefficient was 0.999, and the regression equation was $\text{Paramax}^{\circledR} \text{ value} = (1.16 \times \text{aca value}) - 1.8 \text{ mg/dL}$. The data indicates that the results obtained by both reagents are substantially equivalent.