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Summary of Safety and Effectiveness Information

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

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.

Submitter's Name: Rebecca S. Ayash
Dade International Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: 1/31/97

Name of Product: Human Chorionic Gonadotropin Calibrator

FDA Classification Name: Calibrator

Predicate Device: aca® plus Human Chorionic Gonadotropin Calibrator

Device Description: The Human Chorionic Gonadotropin (HCG) Calibrator for the Dimension® RxL system is a lyophilized horse serum-based product. The Level 1 calibrator contains no detectable hCG. Levels 2 through 5 contain human urine chorionic gonadotropin. The kit consists of ten vials; two at each of five levels.

Intended Use: The HCG Calibrator is intended to be used to calibrate the HCG method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.

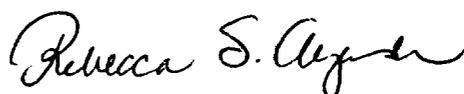
Comparison to Predicate Device:

	Dimension® RxL HCG Calibrator	aca® plus HCG Calibrator
Intended Use	Calibrator	Calibrator
Analytes	Human Chorionic Gonadotropin	Human Chorionic Gonadotropin
Matrix	horse serum	horse serum
Form	lyophilized	lyophilized
Volume	2.0 mL per vial, reconstituted	3.0 mL per vial, reconstituted
Levels	5 levels	3 levels

Comments on Substantial

Equivalence: Both the HCG Calibrator for the Dimension® RxL system and the aca® plus HCG Calibrator are horse serum based products containing human urine chorionic gonadotropin as the analyte source and are intended to be used as calibrators for human chorionic gonadotropin assays.

Conclusion: The HCG Calibrator for the Dimension® RxL system is substantially equivalent to the aca® plus HCG Calibrator based on the comparison summarized above.



Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
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