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Interoffice Memorandum

Summary of Safety and Effectiveness Information

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: Cathy P. Craft
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Date of Preparation: 01/27/1997

Name of Product: MMB Calibrator

FDA Classification Name: Calibrator

Predicate Device: Abbott Laboratories*IMx® Stat CK-MB Calibrator

Device Description: The MMB Calibrator is a lyophilized horse serum-based product. The Level 1 calibrator contains no detectable CKMB. Levels 2 through 5 contain human CKMB. The kit consists of ten vials; two at each of five levels.

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

Comparison to Predicate Device:

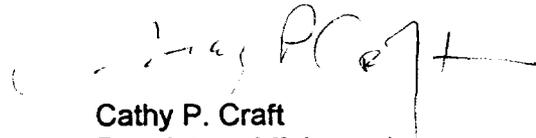
<u>Item</u>	<u>MMB Calibrator</u>	<u>IMx® Stat CK-MB Calibrator</u>
Intended Use	Calibrator	Calibrator
Analytes	CKMB	CKMB
Matrix	horse serum	bovine serum
Form	lyophilized	liquid
Volume	2.0 mL per vial, reconstituted	4.0 mL per vial
Levels	5 levels	6 levels

* IMx® is a trademark of Abbott Laboratories, Abbott Park, IL 60064

Comments on Substantial

Equivalence: Both the MMB Calibrator for the Dimension® RxL system and the Abbott IMx® Stat CK-MB Calibrator are intended to be used as calibrators for CKMB methods.

Conclusion: The MMB Calibrator is substantially equivalent to the IMx® Stat CK-MB Calibrator based on the comparison discussed above.



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Regulatory Affairs and
Compliance Manager
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