

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.

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Date of Preparation: 8/29/96

Name of Product: Ferritin Calibrator

FDA Classification Name: Calibrator

Predicate Device: Abbott Laboratories*IMx® Ferritin Calibrator

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

Intended use: The Ferritin Calibrator is intended to be used to calibrate the ferritin (FERR) method on the Dimension® RxL clinical chemistry system.

Comparison to Predicate Device:

<u>Item</u>	<u>Ferritin Calibrator</u>	<u>IMx® Ferritin Calibrator</u>
Intended Use	Calibrator	Calibrator
Analytes	ferritin	ferritin
Matrix	bovine serum base	buffered aqueous base
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 Ferritin Calibrator and the Abbott IMx® Ferritin Calibrator are intended to be used as calibrators for ferritin methods.

Conclusion: The Ferritin Calibrator is substantially equivalent to the IMx® Ferritin Calibrator based on the comparison discussed above.

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