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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: 12/03/96

Name of Product: Ferritin Flex™ Reagent Cartridge

FDA Classification Name: FerritinTest System

Predicate Device: Abbott Laboratories IMx® Ferritin

Device Description: The FERR Flex™ Reagent Cartridge is a one-step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles, coated with monoclonal antibodies specific for ferritin and conjugate reagent consisting of β -galactosidase labeled monoclonal antibodies specific for a second binding site on ferritin to form a particle-ferritin-conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β -galactosidase is combined with a chromogenic substrate chlorophenil red-b-d-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore (CPR). The color change at 577 nm is directly proportional to the concentration of ferritin in the original sample.

Intended Use: The FERR Flex™ reagent cartridge is used on the Dimension™ RxL clinical chemistry system to quantitatively measure ferritin in human serum and plasma.

Comparison to Predicate Device:

<u>Item</u>	<u>Dimension® RxL Ferritin</u>	<u>Imx® Ferritin</u>
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577nm and 700nm	Fluorometric endpoint measurement

Comments on Substantial

Equivalence: Split sample comparison between the FERR Flex™ reagent cartridge on the Dimension® RxL clinical chemistry system and the Abbott IMx® assay gave a correlation coefficient of 0.983, slope of 0.98, and an intercept of -0.8 ng/mL when tested with 60 clinical patient samples.

Conclusion: The FERR Flex™ Reagent Cartridge is substantially equivalent in principle and performance to the Imx® Ferritin Assay based on the split sample comparison discussed above.



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Regulatory Affairs and
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