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Beckman Instruments, Inc., Section 510(k) Notification
IMMAGE™ Immunochemistry System Transferrin (TRF) Reagent
Summary of Safety & Effectiveness

K963427

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IMMAGE™ Immunochemistry System Transferrin (TRF) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

30 August 1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Transferrin (TRF) Reagent

3.2 **Classification Names**

Transferrin immunological test system (21 CFR 866.5880)

4.0 **Predicate Device(s):**

Beckman Immunochemistry Systems TRF Transferrin Reagent

5.0 **Description:**

The IMMAGE Immunochemistry System Transferrin (TRF) Reagent is used in the determination of transferrin concentrations in human serum samples on Beckman's IMMAGE Immunochemistry System. The reagent kit contains one cartridge of reagent, evaporation caps and a lot specific bar code card. Calibrators and control materials are purchased separately.

6.0 **Intended Use:**

The IMMAGE Immunochemistry System Transferrin (TRF) reagent, in conjunction with Beckman Calibrator 1, is intended for use in the quantitative determination of transferrin concentrations in human serum samples by rate nephelometry.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System (TRF) Reagent	Assay method - rate nephelometry	Same as Beckman's Immunochemistry System Transferrin TRF Reagent as run on the ARRAY® System
	Analytic Range 75 - 750 mg/dL Extended Range 12.5 - 4,500 mg/dL	
	Sample and reagent ratios	
	Antibody	
	Shelf life of 24 months (stored at 2 -8°C)	
DIFFERENCES		
IMMAGE System (TRF) Reagent	Reaction Temperature	IMMAGE System TRF assays run at 37°C and the predicate runs at 26.7°C
	Reagent container	IMMAGE reagent is stored in a plastic cartridge where as the predicate is stored in glass.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from Beckman's Immunochemistry System TRF Transferrin (on ARRAY) Reagent to the IMAGE System TRF Reagent.

Method Comparison Study Results IMAGE TRF Reagent vs. Beckman TRF Transferrin Reagent (on ARRAY)

Analyte	Slope	Intercept	r	Predicate
IMAGE TRF	0.990	0.692	0.994	Beckman's TRF Transferrin Reagent on the ARRAY® Systems

Stability Study Results

Reagent	Product Claim
IMAGE TRF Reagent System	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Within-Run Imprecision

MATERIAL	MEAN (mg/dL)	SD (mg/dL)	%CV	Number of Results
TRF Reagent				
Level 1	241	7.4	3.1	80
Level 2	361	14.0	3.9	80
Level 3	653	18.9	2.9	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.