

K964781
MAY 9, 1997

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Prealbumin (PAB) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

22 November 1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Prealbumin (PAB) Reagent

3.2 **Classification Names**

Prealbumin immunological test system (21 CFR 866.5060)

4.0 **Predicate Device(s):**

Beckman Immunochemistry Systems PAB Prealbumin Reagent

5.0 **Description:**

The IMMAGE Immunochemistry System Prealbumin (PAB) Reagent, in conjunction with Beckman Calibrator 3, is intended for use in the quantitative determination of human prealbumin concentrations in human serum samples. 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 IMAGE Immunochemistry System Prealbumin (PAB) reagent, in conjunction with Beckman Calibrator 3, is intended for use in the quantitative determination of human prealbumin concentrations in human serum samples by rate nephelometry. This assay is designed for use with the Beckman IMAGE Immunochemistry System.

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		
IMAGE System (PAB) Reagent	Assay method - rate nephelometry ✓	Same as Beckman's Immunochemistry System Prealbumin PAB Reagent as run on the ARRAY® System
	Serum: Analytic Range: 7.0 - 50 mg/dL ✓ Extended Range: 1.17 - 1800 mg/dL	
	Sample and reagent ratios ✓	
	Antibody source (goat) ✓	
	Shelf life of 24 months ✓ (stored at 2 -8°C)	
DIFFERENCES		
IMAGE System (PAB) Reagent	Reaction Temperature	IMAGE System PAB assays run at 37°C and the predicate runs at 26.7°C
	Buffer/Reagent Volume	IMAGE System PAB Reagent uses one half the volume utilized by the Array System for the PAB assay

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 the Beckman Immunochemistry System PAB Prealbumin (on ARRAY) Reagent to the IMAGE System PAB Reagent.

Method Comparison Study Results
 IMAGE PAB Reagent vs.
 Beckman Prealbumin Reagent (PAB) on ARRAY

Analyte	Sample Type	Slope	Intercept	r	n	Predicate
IMAGE PAB	Serum	0.992	-0.307	0.985	124	Beckman Prealbumin Reagent (PAB) on the ARRAY® Systems

Stability Study Results

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

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

Precision Study Results
IMMAGE PAB Reagent

Material Serum	Mean (mg/dL)	SD (mg/dL)	%CV	N
Within Run Precision				
Level 1	16.4	0.29	1.8	80
Level 2	25.5	0.51	2.0	80
Level 3	44.7	0.72	1.6	80
Total Precision				
Level 1	16.4	0.33	2.0	80
Level 2	25.5	0.59	2.3	80
Level 3	44.7	0.81	1.8	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.