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K966257

BECKMAN

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Alpha$_1$-Acid Glycoprotein (AAG) Reagent

MAR 24 1997

1.0 **Submitted By:**

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2.0 **Date Submitted:**

24 October 1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Alpha$_1$-Acid Glycoprotein (AAG) Reagent

3.2 **Classification Name**

Alpha-1-glycoproteins immunological test system (21 CFR § 866.5420)

4.0 **Predicate Device(s):**

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Alpha$_1$-Acid Glycoprotein (AAG)	Beckman Alpha$_1$-Acid Glycoprotein Reagent	Beckman Instruments, Inc.	K791341

5.0 Description:

The IMMAGE Immunochemistry System AAG Reagent in conjunction with Beckman Calibrator 1, is intended for use in the quantitative determination of alpha$_1$-acid glycoprotein concentrations respectively in human serum samples on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Alpha$_1$-Acid Glycoprotein (AAG) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of human alpha$_1$-acid glycoprotein 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 AAG Reagent	Initial Analytic Range	Same as Beckman AAG Reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System AAG Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for AAG.
	Antibody concentration	IMMAGE AAG has a higher antibody concentration than the Beckman Alpha$_1$-Acid Glycoprotein reagent.

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 Reagents to the IMMAGE System Reagents.

Method Comparison Study Results

IMMAGE Alpha-1-Acid Glycoprotein (AAG) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE AAG Reagent	serum	0.954	1.62	0.994	141	Beckman AAG Reagent on Array® 360

Stability Study Results

Reagent	Product Claim
IMMAGE AAG	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Within-Run Imprecision

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
		AAG		
Level 1	75.5	1.45	1.9	80
Level 2	183	2.2	1.2	80
Level 3	251	3.1	1.2	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.