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BECKMAN

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Kappa (KAP) and Lambda (LAM) Light Chain Reagents

K964260

1.0 Submitted By:

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2.0 Date Submitted:

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3.0 Device Name(s):

3.1 Proprietary Names

IMMAGE™ Immunochemistry System Kappa Light Chain (KAP) Reagent
IMMAGE™ Immunochemistry System Lambda Light Chain (LAM) Reagent

3.2 Classification Name

Immunoglobulin (light chain specific) immunological test system (21 CFR § 866.5550)

4.0 Predicate Device(s):

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Kappa (KAP) Reagent	Beckman Kappa Light Chain (KAP) Reagent	Beckman Instruments, Inc.	K884276A K902484
IMMAGE System Lambda (LAM) Reagent	Beckman Lambda Light Chain (LAM) Reagent	Beckman Instruments, Inc.	K884597A K902484

5.0 Description:

The IMMAGE Immunochemistry System KAP and LAM Reagents in conjunction with Beckman Calibrator 1, are intended for use in the quantitative determination of kappa and lambda light chain concentrations respectively in human serum and urine samples on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Kappa (KAP) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of kappa light chains (free and bound) by rate nephelometry.

The IMMAGE Immunochemistry System Lambda (LAM) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of lambda light chains (free and bound) 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 KAP and LAM Reagents	Initial Analytic Range	Same as Beckman Kappa and Lambda Light Chain reagents
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System KAP and LAM Reagents	Antigen excess testing solution	IMMAGE KAP & LAM have antigen excess testing solution included in the reagent cartridge, while the Beckman Kappa and Lambda require off-line preparation of the solution.
	Antibody concentration	IMMAGE KAP and LAM have a higher antibody concentration than the Beckman Kappa and Lambda reagents

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 Kappa (KAP) and Lambda (LAM) Reagents

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE KAP Reagent	serum	1.037	-9.16	0.987	220	Beckman KAP Reagent
	urine	0.970	1.36	0.980	103	
IMMAGE LAM Reagent	serum	1.020	-23.5	0.991	236	Beckman LAM Reagent
	urine	1.009	-0.08	0.954	40	

Stability Study Results

Reagent	Product Claim
IMMAGE KAP & LAM	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
Kappa Light Chain (KAP) Serum				
Level 1	540	15.6	2.9	80
Level 2	1113	24.1	2.2	80
Level 3	2377	61.2	2.6	80

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Kappa Light Chain (KAP) Urine				
Level 1	2.33	0.059	2.5	30
Level 2	9.34	0.236	2.5	30
Level 3	19.2	0.25	1.3	30

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Lambda Light Chain (LAM) Serum				
Level 1	247	5.1	2.1	80
Level 2	718	14.0	1.9	80
Level 3	1233	37.2	3.0	80

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Lambda Light Chain (LAM) Urine				
Level 1	8.69	0.204	2.4	30
Level 2	17.1	0.20	1.2	30
Level 3	30.0	0.89	3.0	30

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.