

BECKMAN

Summary of Safety & Effectiveness
IMAGE™ Immunochemistry System Immunoglobulins IGG, IGA, & IGM Reagents

K963868

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1.0 Submitted By:

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2.0 Date Submitted:

25 September-1996

3.0 Device Name(s):

3.1 Proprietary Names

IMAGE™ Immunochemistry System Immunoglobulin G (IGG) Reagent
 IMAGE™ Immunochemistry System Immunoglobulin A (IGA) Reagent
 IMAGE™ Immunochemistry System Immunoglobulin M (IGM) Reagent

3.2 Classification Names

Immunoglobulin G Test System (21 CFR §866.5510)
 Immunoglobulin A Test System (21 CFR §866.5510)
 Immunoglobulin M Test System (21 CFR §866.5510)

4.0 Predicate Device(s):

IMAGE System Reagent	Predicate	Manufacturer	Docket Number
Immunoglobulin G (IGG) Reagent	Immunochemistry Systems Immunoglobulin G Reagent	Beckman Instruments, Inc.	K771603
Immunoglobulin A (IGA) Reagent	Immunochemistry Systems Immunoglobulin A Reagent	Beckman Instruments, Inc.	K771603
Immunoglobulin M (IGM) Reagent	Immunochemistry Systems Immunoglobulin M Reagent	Beckman Instruments, Inc.	K771603

Beckman Instruments, Inc.

5.0 Description:

The IMMAGE Immunochemistry System Immunoglobulins IGG, IGA, and IGM, Reagents in conjunction with Beckman Calibrator 1, are intended for use on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Immunoglobulin G (IGG) reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of human immunoglobulin G by rate nephelometry.

The IMMAGE Immunochemistry System Immunoglobulin A (IGA) reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of human immunoglobulin A by rate nephelometry.

The IMMAGE Immunochemistry System Immunoglobulin M (IGM) reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of human immunoglobulin M 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 (IGG, IGA, & IGM) Reagents	Reagent antibody formulation	Same as Immunochemistry Systems (IGG, IGA, & IGM) Reagents
	Nephelometric rate methodology	
	Reagents are curve fit with the same standards	
DIFFERENCES		
IMMAGE System (IGG, IGA, & IGM) Reagents	Antibody titer	Immunochemistry Systems (IGG, IGA, & IGM) reagents use a higher antibody titer.
IMMAGE System (IGG, IGA, & IGM) Reagents	Reaction Temperature	Immunochemistry Systems operate at 26°C, IMMAGE System operates at 37°C

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 Immunochemistry Systems Reagents to the IMMAGE System Reagents.

**Method Comparison Study Results
 IMMAGE System IGG, IGA, & IGM Reagents**

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE IGG Reagent	Serum	1.037	-16.6	0.971	323	Immunochemistry Systems IGG Reagent
IMMAGE IGG Reagent	CSF	1.037	0.11	0.985	100	Immunochemistry Systems IGG Reagent
IMMAGE IGA Reagent	Serum	1.031	-2.07	0.990	289	Immunochemistry Systems IGA Reagent
IMMAGE IGM Reagent	Serum	1.001	-4.29	0.998	247	Immunochemistry Systems IGM Reagent

Stability Study Results

Reagent	Product Claim
IMMAGE IGG, IGA, & IGM	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Within-Run Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin G (IGG) (Serum sample)				
Level 1	549	10.8	2.0	80
Level 2	1293	33.3	2.6	80
Level 3	2362	51.2	2.2	80

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin G (IGG) Reagent (CSF sample)				
Level 1	1.62	0.086	5.3	30
Level 2	7.85	0.104	1.3	30
Level 3	13.5	0.52	3.9	30

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin A (IGA) Reagent				
Level 1	126	3.7	2.9	80
Level 2	268	7.6	2.8	80
Level 3	605	15.4	2.5	80

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin M (IGM) Reagent				
Level 1	53.8	1.56	2.9	80
Level 2	115	2.7	2.4	80
Level 3	334	10.6	3.2	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.