200 South Kraemer Boulevard, Box 8000, Brea, CA 92822-8000 • (714) 993-5321

K963974

BECKMAN

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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Urine Immunoglobulin G (IGU) Reagent

1.0 Submitted By:

Annette Hellie
Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4457

2.0 Date Submitted:

30 September 1996

3.0 Device Name(s):

3.1 Proprietary Name

IMMAGE™ Immunochemistry System Urine Immunoglobulin G (IGU) Reagent

3.2 Classification Name

Immunoglobulins A, G, M, D, and E immunological test system (21 CFR § 866.5510)

4.0 Predicate Device(s):

Beckman Immunoglobulin G (IGG) Test System (Urine application) K951635

5.0 Description:

The IMMAGE Immunochemistry System Urine Immunoglobulin G (IGU) reagent, in conjunction with Beckman's Urine Protein Calibrator, is intended for use in the quantitative determination of Immunoglobulin G in human urine samples.

6.0 Intended Use:

The IMMAGE Immunochemistry System Urine Immunoglobulin G (IGU) reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Urine Protein Calibrator, is intended for the quantitative determination of Immunoglobulin G in urine 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 IGU Reagent	Analytic Range	Same as Beckman IGG Test System reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System IGU Reagent	Antigen excess testing	IMMAGE IGU has antigen excess testing solution included in the reagent cartridge, while the Beckman IGG Test System requires off-line preparation of the solution.
	Antibody concentration	IMMAGE IGU has a higher antibody concentration than the Beckman IGG Test System

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 Immunoglobulin G Test System Reagent to the IMMAGE IGU Reagent.

Method Comparison Study Results
IMMAGE IGU Reagent vs. Beckman Immunoglobulin G Kit Reagent

Analyte	Slope	Intercept	r	n	Predicate
IMMAGE IGU Reagent	1.00	0.00	0.998	115	Beckman (IGG) Test System

Stability Study Results

Reagent	Product Claim
IMMAGE IGU	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
IGU Reagent				
Level 1	0.38	0.038	10.2	80
Level 2	2.66	0.071	2.7	80
Level 3	5.20	0.140	2.7	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.