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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Haptoglobin (HPT) Reagent

1.0 Submitted By:

Margie George
Project Manager, System Development
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 961-3765
FAX: (714) 961-3759

2.0 Date Submitted:

23 Aug-1996

3.0 Device Name(s):

3.1 Proprietary Names

IMMAGE™ Immunochemistry System Haptoglobin (HPT) Reagent

3.2 Classification Names

Haptoglobin immunological test system(21 CFR 866.5460)

4.0 Predicate Device(s):

Beckman Immunochemistry Systems HPT Haptoglobin Reagent

5.0 Description:

The IMMAGE Immunochemistry System Haptoglobin (HPT) reagent, in conjunction with Beckman Calibrator 1, is intended for use in the quantitative determination of human haptoglobin concentrations in human serum samples.

6.0 Intended Use:

The IMMAGE Immunochemistry System Haptoglobin (HPT) reagent, in conjunction with Beckman Calibrator 1, is intended for use in the quantitative determination of human haptoglobin concentrations in human serum samples by rate nephelometry. This assay is designed for use with Beckman's IMMAGE 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		
IMMAGE System (HPT) Reagent	Assay method - rate nephelometry	Same as Beckman's HPT Haptoglobin Reagent
	Analytic Range 35 - 350 mg/dL Extended Range 5.8 - 12,600 mg/dL	Same as Beckman's HPT Haptoglobin Reagent
	Sample and reagent ratios	Same as Beckman's HPT Haptoglobin Reagent
	Antibody	Same as Beckman's HPT Haptoglobin Reagent
	Shelf life of 24 months (stored at 2-8°C)	Same as Beckman's HPT Haptoglobin Reagent
DIFFERENCES		
IMMAGE System (HPT) Reagent	Reaction Temperature	IMMAGE System HPT assays run at 37°C and the predicate runs at 26.7°C
	Antigen excess solution (AGXS)	IMMAGE System HPT Reagent AGXS is prediluted and present in the reagent cartridge while the predicate requires off-line preparation of the solution.

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 Haptoglobin Reagent to the IMAGE HPT Reagent.

Method Comparison Study Results
 IMAGE HPT Reagent vs. Beckman Haptoglobin Reagent

Analyte	Slope	Intercept	r	Predicate
IMAGE HPT	1.004	-6.80	0.996	Beckman's HPT Haptoglobin Reagent on the Array® Systems

Stability Study Results

Reagent	Product Claim
IMAGE HPT	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
HPT Reagent				
Level 1	60.8	0.87	1.4	80
Level 2	136	3.4	2.5	80
Level 3	322	9.7	2.8	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.