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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System

K962294

1.0 Submitted By

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2.0 Date Submitted

15 June 1996

3.0 Device Name(s)

3.1 Proprietary Names

IMMAGE™ Immunochemistry System

3.2 Classification Names

Nephelometer for clinical use (21 CFR 862.2700)
Discrete photometric chemistry analyzer for clinical use (21 CFR 862.2160)

4.0 Predicate Device(s)

Beckman ARRAY® 360 Immunochemistry System and Reagents (K922273, K771603, K780913, K926272, K862019, K810306)
Seradyn LPIA-100 Instrument (K924186/A)
Abbott TDx Immunochemistry Reagents (K882233, K932127)
Behring N Latex RF (K942328)

5.0 Description

The IMMAGE Immunochemistry System is a fully automated, computer controlled, bench-top chemistry analyzer intended for the *in vitro* quantitative determination of specific components and therapeutic drugs of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid. The analyzer operates in conjunction with reagents, calibrators, and controls designed for use with the system. The instrument features barcode identification of samples and reagents. It automatically dilutes samples and delivers them to the reaction cuvette along with reagents and reaction constituents. The system analyzes up to 72 samples per run with up to 24 analytes per sample. Major hardware components include a reagent compartment, sample and reagent cranes, reaction module, sample carousel and crane, hydropheumatics, electronics, and power supplies.

6.0 Intended Use

The IMMAGE Immunochemistry System is a fully automated, computer controlled, bench-top chemistry analyzer intended for the *in vitro* quantitative measurement of therapeutic drugs and specific components of clinical use in biological fluids.

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7.0 Comparison to Predicate(s)

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Aspect/Characteristic	Comments
SIMILARITIES	
Intended for: *in vitro* diagnostic quantitation of components of biological fluids by rate nephelometry and nephometric inhibition	same as ARRAY System
Measures nephelometric increase in light scatter due to immunoprecipitin formation between antigen and antibody	same as ARRAY System
Uses nephelometric inhibition immunoassay to measure drugs and small molecular weight constituents	same as ARRAY System
Uses non-linear math models to describe standard curve determined during reagent manufacturing and a single point calibration for routine instrument operation	same as ARRAY System
Uses plastic reaction cuvettes which are washed between samples	same as ARRAY System
Measures turbidimetric decrease in transmitted light due to immunoprecipitin formation between antigen and antibody where one is coupled to latex particles	same as LPIA 100
Mathematically calculated absorbance units from the measured transmitted light intensity and calculated rate of change of absorbance during reaction	same as LPIA 100
Measures turbidimetric transmitted light scatter in the forward direction (0°- 15°)	same as LPIA 100
Cuvette light path 7 mm and reaction incubation temperature controlled at 37°C	same as LPIA 100
DIFFERENCES	
IMMAGE System uses visible laser diode at 670 nm as the light source for nephelometry	ARRAY System uses a tungsten halogen lamp at 400-620
IMMAGE System detects light scatter at 90° from the incident beam angle	ARRAY System detects light scatter at 70° angle
IMMAGE System maintains reaction temperature at 37°C	ARRAY System maintains reaction temperature at 26.7°C
IMMAGE System uses a LED at 940 nm as light source for turbidimetry	LPIA-100 uses a tungsten halogen light source at 950 nm
IMMAGE uses non-linear math models to describe standard curves during reagent manufacture and a single point calibration for routine instrument operation	LPIA-100 uses linear and quadratic math models with a multipoint calibration during operation
IMMAGE uses washable plastic reaction cuvettes	LPIA-100 uses disposable plastic reaction cuvettes

8.0 Summary of Performance Data

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to *in vitro* diagnostic test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments that relate results obtained from the IMMAGE Immunochemistry System to selected predicate methods.

Method Comparison Study Results
IMMAGE Immunochemistry System vs Selected Predicate Methods

Analyte	Slope	Intercept	r	Predicate
Apolipoprotein A	0.9958	1.78	0.985	ARRAY System
Complement C3	0.9789	8.05	0.990	ARRAY System
Digoxin	1.0637	-0.02	0.968	Abbott TDx*
Immunoglobulin A	1.0281	-4.61	0.995	ARRAY System
Rheumatoid Factor	1.0545	0.41	0.940	Behring N Latex RF
Theophylline	0.9917	0.12	0.955	Abbott TDx
Transferrin/serum	1.0316	-10.06	0.985	ARRAY System
Transferrin/urine	1.1108	-0.04	0.998	ARRAY System

*TDx is a registered tradmark of Abbott Diagnostics

Estimated Within-run Imprecision

MATERIAL	MEAN	SD	%CV	N
Apolipoprotein A (mg/dL)				
Level 1	56.0	1.92	3.4	80
Level 2	103	2.6	2.5	80
Level 3	163	2.5	1.5	80
Complement C3 (mg/dL)				
Level 1	67.1	1.3	1.9	80
Level 2	102	2.2	2.1	80
Level 3	395	8.7	2.2	80
Digoxin (ng/mL)				
Level 1	1.18	0.063	5.3	80
Level 2	2.47	0.177	7.2	80
Level 3	4.16	0.109	2.6	80

Immunoglobulin A (mg/dL)				
Level 1	123	2.1	1.7	80
Level 2	261	3.4	1.3	80
Level 3	599	19.2	3.2	80
Rheumatoid Factor (IU/mL)				
Level 1	123	1.5	1.2	80
Level 2	290	3.1	1.1	80
Level 3	613	8.7	1.4	80
Theophylline (µg/mL)				
Level 1	8.12	0.17	2.2	80
Level 2	19.9	0.30	1.5	80
Level 3	32.4	0.46	1.4	80
Transferrin/serum (mg/dL)				
Level 1	241	6.8	2.8	80
Level 2	364	15.2	4.2	80
Level 3	680	17.9	2.6	80
Transferrin/urine (mg/dL)				
Level 1	0.38	0.008	2.2	80
Level 2	1.56	0.042	2.7	80
Level 3	3.06	0.124	4.1	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.