K965108

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Summary of Safety & Effectiveness
SYNCHRON LX™ Systems Immunoglobulin G, A, and M (Ig-G, Ig-A, & Ig-M) Reagents

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**

SYNCHRON LX™ Systems Immunoglobulin G (Ig-G) Reagent
SYNCHRON LX™ Systems Immunoglobulin A (Ig-A) Reagent
SYNCHRON LX™ Systems Immunoglobulin M (Ig-M) 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):**

SYNCHRON LX Reagents	Predicate	Predicate Company	Docket Number
Immunoglobulin G (Ig-G) Reagent	Beckman Immunoglobulin G (IGG) Reagent	Beckman Instruments, Inc.	K771603
Immunoglobulin A (Ig-A) Reagent	Beckman Immunoglobulin A (IGA) Reagent	Beckman Instruments, Inc.	K771603
Immunoglobulin M (Ig-M) Reagent	Beckman Immunoglobulin M (IGM) Reagent	Beckman Instruments, Inc.	K771603

5.0 **Description:**

The SYNCHRON LX™ Systems Immunoglobulin G, A, and M (Ig-G, Ig-A, Ig-M) Reagents in conjunction with SYNCHRON LX Calibrator 1, are intended for use on Beckman's SYNCHRON LX Clinical Systems.

6.0 **Intended Use:**

The SYNCHRON LX Systems Immunoglobulin G (Ig-G) reagent, when used in conjunction with SYNCHRON LX Calibrator 1, is intended for the quantitative determination of human immunoglobulin G in serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON LX™20 Clinical System.

The SYNCHRON LX Systems Immunoglobulin A (Ig-A) reagent, when used in conjunction with SYNCHRON LX Calibrator 1, is intended for the quantitative determination of human immunoglobulin A in serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON LX™20 Clinical System.

The SYNCHRON LX Systems Immunoglobulin M (Ig-M) reagent, when used in conjunction with SYNCHRON LX Calibrator 1, is intended for the quantitative determination of human immunoglobulin M in serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON LX™20 Clinical System.

7.0 **Comparison to Predicate(s):**

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

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON LX Systems Immunoglobulin (Ig-G, Ig-A, & Ig-M) Reagents	Intended Use	Same as Beckman Immunoglobulin reagents; quantitative determination of human immunoglobulins
	Chemical Reaction	Same principle as the Immunoglobulin Beckman Reagents; formation of antigen-antibody complex
	Antibody	Same source, antibody, processing, and buffer as Beckman Immunoglobulin reagents
	Range Expansion	Same as the Beckman Immunochemistry (ARRAY) System which expands usable range with alternate sample dilution ratios
	Calibration	Same as the Beckman Immunoglobulin reagents; single point update of manufacturer-determined calibration curve.

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON LX Systems Immunoglobulin (Ig-G, Ig-A, & Ig-M) Reagents	Methodology	The SYNCHRON LX reads turbidimetrically and the ARRAY Systems read nephelometrically
	Measurement Method	The SYNCHRON LX runs the reaction at 37°C and reads an endpoint at 340 nm; the ARRAY Systems run at 26.5°C and read at a peak rate at 450-550 nm
	Antigen Excess Checking	The SYNCHRON LX Reagents ere designed so that high antigen concentration will not report in range; the ARRAY Systems add extra antibody to observe for additional activity.
	Sample Diluent	The SYNCHRON LX uses a tris buffer for sample dilution; the ARRAY Systems use a phosphate buffered diluent.
	Reagent Storage	The SYNCHRON LX reagents are stored refrigerated onboard the instrument; the ARRAY Systems reagents are stored at room temperature onboard the instrument/ refrigerated when not in use.
	Packaging	The SYNCHRON LX reagents are packaged in polystyrene cartridges; the ARRAY Systems reagents are in glass bottles.

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 Reagents (IGG, IGA, IGM) to the SYNCHRON LX Systems Immunoglobulin Reagents (Ig-G, Ig-A, Ig-M).

Method Comparison Study Results
SYNCHRON LX Systems Ig-G, Ig-A, & Ig-M Reagents

Reagent	Slope	Intercept	r	n	Predicate Method
SYNCHRON LX Immunoglobulin G Reagent (Ig-G)	0.928	72.7	0.9970	82	Beckman's Immunoglobulin IGG Reagent
SYNCHRON LX Immunoglobulin A Reagent (Ig-A)	0.924	0.68	0.9962	78	Beckman's Immunoglobulin IGA Reagent
SYNCHRON LX Immunoglobulin M Reagent (Ig-M)	1.051	-17.19	0.9914	72	Beckman's Immunoglobulin IGM Reagent

Estimated Within-Run Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin G (Ig-G)				
Level 1	527	6.9	1.3	80
Level 2	1103	16.1	1.5	80

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin A (Ig-A)				
Level 1	109	1.8	1.7	80
Level 2	242	4.0	1.7	80

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Immunoglobulin M (Ig-M) Reagent				
Level 1	46.6	1.8	3.9	80
Level 2	103.5	2.3	2.2	80

Stability Study Results

Reagent	Product Claim
SYNCHRON LX Systems Immunoglobulin G, A, & M Reagents	24 month shelf-life 14 day calibration stability 60 days on-board stability

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.