

K970314

Summary of Safety & Effectiveness  
SYNCHRON LX™ Systems Apolipoprotein ApoA and ApoB Reagents

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1.0 **Submitted By:**

Kathleen M. Jaker  
Senior Applications Chemist  
Beckman Instruments, Inc.  
200 S. Kraemer Blvd., W-117  
Brea, California 92822-8000  
Telephone: (714) 961-3970  
FAX: (714) 961-4457

2.0 **Date Submitted:**

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3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON LX™ Systems Apolipoprotein A-1 (ApoA) Reagent  
SYNCHRON LX™ Systems Apolipoprotein B (ApoB) Reagent

3.2 **Classification Names**

Lipoprotein Test System (21 CFR §862.1475)

4.0 **Predicate Device(s):**

SYNCHRON LX Reagents	Predicate	Predicate Company	Docket Number
Apolipoprotein A-1 (ApoA) Reagent	Beckman Apolipoprotein A-1 (APA) Reagent	Beckman Instruments, Inc.	K862019
Apolipoprotein B (ApoB) Reagent	Beckman Apolipoprotein B (APB) Reagent	Beckman Instruments, Inc.	K862386

5.0 **Description:**

The SYNCHRON LX™ Systems Apolipoprotein ApoA and ApoB Reagents in conjunction with SYNCHRON Systems APO CAL, are intended for use on Beckman's SYNCHRON LX Clinical Systems.

6.0 **Intended Use:**

The SYNCHRON LX Systems Apolipoprotein A-1 (ApoA) reagent, when used in conjunction with SYNCHRON Systems APO CAL, is intended for the quantitative determination of human apolipoprotein A-1 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 Apolipoprotein B (ApoB) reagent, when used in conjunction with SYNCHRON Systems APO CAL, is intended for the quantitative determination of human apolipoprotein B 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 with the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON LX System (ApoA and ApoB) Reagents	Intended Use	Same as Beckman's Apolipoprotein reagents; quantitative determination of human apolipoproteins A-1 and apolipoprotein B.
	Chemical Reaction	Same principle as the predicate; formation of antigen-antibody complex
	Antibody	Same source, processing as Beckman Apolipoprotein reagents
	Calibration	Same as the ARRAY systems reagents; single point update of manufacturer-determined calibration curve.

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON LX System (ApoA and ApoB) Reagents	Methodology	The SYNCHRON LX reads turbidimetrically and the Immunochemistry systems (ARRAY) 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
	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 Apolipoprotein Reagents (APA and APB) to the SYNCHRON LX Systems Apolipoprotein Reagents (ApoA and ApoB).

Method Comparison Study #1 Results  
 SYNCHRON LX Systems ApoA & ApoB Reagents

Reagent (Analyte)	Slope	Intercept (mg/dL)	r	n	Predicate Method
SYNCHRON LX Apolipoprotein A-1 Reagent (ApoA)	0.953	4.1	0.9922	78	Beckman's Apolipoprotein APA Reagent
SYNCHRON LX Apolipoprotein B Reagent (ApoB)	0.943	7.6	0.9970	73	Beckman's APB Reagent

Method Comparison Study #2 Results  
 SYNCHRON LX Systems ApoA & ApoB Reagents

Reagent	Slope	Intercept (mg/dL)	r	n	Predicate Method
SYNCHRON LX Apolipoprotein A-1 Reagent (ApoA)	1.022	-3.4	0.965	54	NWLRL* Nephelometric Procedure
SYNCHRON LX Apolipoprotein B Reagent (ApoB)	1.006	1.7	0.991	54	NWLRL* Nephelometric Procedure

\* NWLRL = Northwest Lipid Research Laboratories

Estimated Within-Run Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
<b>Apolipoprotein A-1 (ApoA)</b>				
Level 1	94.4	2.07	2.19	80
Level 2	121.6	2.12	1.74	80
Level 3	145.6	1.80	1.23	80

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
<b>Apolipoprotein B (ApoB)</b>				
Level 1	59.6	0.98	1.65	80
Level 2	96.2	1.94	2.02	80
Level 3	132.8	1.77	1.33	80

Stability Study Results

Reagent	Product Claim
SYNCHRON LX Systems Apolipoprotein ApoA and ApoB	24 month shelf-life 14 day calibration stability 30 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.