AUG - 7 2003

K032035

510(k) Summary
SYNCHRON LX® Systems
Complement C3 Reagent, Complement C4 Reagent and LX Calibrator 1

1.0 **Submitted By:**

Kim Walker
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-4912
FAX: (714) 961-4123

2.0 **Date Submitted:**

June 30, 2003

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON LX® Systems Complement C3 (C3) Reagent
SYNCHRON LX® Systems Complement C4 (C4) Reagent
SYNCHRON LX® Systems Calibrator 1 (CAL1)

3.2 **Classification Name**
Complement components immunological test system (21 CFR § 866.5240)
Clinical Chemistry Test Systems Calibrator (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate	Predicate	Manufacturer	Docket Number
LX Systems C3 and C4 Reagent	Beckman IMMAGE Complement C3 and C4 Reagents	Beckman Coulter	K964842
LX CAL 1	Beckman Calibrator 1	Beckman Coulter	K771603 K791341

*Beckman Coulter, Inc., Brea, CA

5.0 **Description:**

The SYNCHRON LX® C3 and C4 Reagents are designed for optimal performance on the SYNCHRON LX® Systems. The reagent kit contains two 100-test cartridges that are packaged separately from the associated calibrators. The LX CAL 1 kit contains four 3 mL – bottles.

6.0 **Intended Use:**

C3 reagent, when used in conjunction with SYNCHRON LX® Systems and Calibrator 1, is intended for quantitative determination of Complement C3 concentration in human serum or plasma by rate turbidimetry.

C4 reagent, when used in conjunction with SYNCHRON LX® Systems and Calibrator 1, is intended for quantitative determination of Complement C4 concentration in human serum or plasma by turbidimetry.

The Beckman Coulter SYNCHRON LX® Systems Calibrator 1 (CAL 1), used in conjunction with SYNCHRON LX reagents, is intended for the calibration of the immunoprotein tests on SYNCHRON LX Systems.

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
LX System C3 Reagent	Sample Type	Same as Beckman IMMAGE C3 Reagent
	Reference Range	
	Antibody Source	
	Liquid Stable Reagent	
LX System C4 Reagent	Sample Type	Same as Beckman IMMAGE C4 Reagent
	Reference Range	
	Antibody Source	
	Liquid Stable Reagent	
LX System CAL 1	Human Serum Preparation	Same as Beckman CAL 1
	Liquid Stable Calibrator	

Differences From The Predicate

Reagent	Aspect/Characteristic	Comments
LX System C3 Reagent	Analytical Range	The LX C3 range is 10-350 mg/dL whereas the IMMAGE C3 range is 50-500mg/dL
	Assay Method	The LX C3 uses rate turbidimetry whereas the IMMAGE uses rate nephelometry
	Initial dilution range	The LX C3 uses a 1:20 dilution initially and the IMMAGE C3 uses a 1:36 dilution.
	Extended dilution range	The LX C3 does not have an extended range whereas the IMMAGE C3 does.
LX System C4 Reagent	Analytical Range	The LX C4 range is 5-120 mg/dL whereas the IMMAGE C4 range is 10-130 mg/dL
	Assay Method	The LX C4 uses turbidimetry whereas the IMMAGE uses rate nephelometry
	Initial dilution range	The LX C4 uses a 1:20 dilution initially and the IMMAGE C4 uses a 1:36 dilution.
	Extended dilution range	The LX C4 does not have an extended range whereas the IMMAGE C4 does.
LX System CAL 1	Intended Use	The LX CAL 1 is used with the LX Systems (a spectrophotometer) whereas the Beckman CAL 1 is used with the IMMAGE or ARRAY Systems (nephelometers)

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, linearity, and imprecision experiments.

SYNCHRON LX Systems C3 and C4 Method Comparison Study Results

Candidate	Slope	Slope Confidence	Intercept	Intercept Confidence	r	n	Predicate Method
LX C3 Reagent	1.025	0.023	2.307	2.783	0.992	134	IMMAGE C3 Reagent
LX C4 Reagent	1.001	0.027	0.938	0.717	0.985	160	IMMAGE C4 Reagent

SYNCHRON LX System C3 and C4 Estimated Imprecision

LX System C3 Reagent Imprecision Results

Sample	**Mean (mg/dL)**	**SD (mg/dL)**	**% C.V.**	**N**
Within-Run Imprecision				
Serum Control 1	55.6	0.97	1.75	80
Serum Control 2	170.8	2.20	1.29	80
Serum Control 3	237.4	2.27	0.96	80
Serum Pool 1	28.9	0.49	1.71	80
Total Imprecision				
Serum Control 1	55.6	1.21	2.19	80
Serum Control 2	170.8	2.44	1.43	80
Serum Control 3	237.4	2.92	1.23	80
Serum Pool 1	28.9	0.57	1.98	80

LX System C4 Reagent Imprecision Results

Sample	**Mean (mg/dL)**	**SD (mg/dL)**	**% C.V.**	**N**
Within-Run Imprecision				
Serum Control 1	25.1	0.40	1.59	80
Serum Control 2	38.0	0.50	1.32	80
Serum Control 3	50.1	0.85	1.70	80
Serum Pool 1	9.5	0.23	2.37	80
Serum Pool 2	70.3	1.07	1.53	80
Total Imprecision				
Serum Control 1	25.1	0.46	1.82	80
Serum Control 2	38.0	0.64	1.68	80
Serum Control 3	50.1	1.09	2.17	80
Serum Pool 1	9.5	0.29	3.09	80
Serum Pool 2	70.3	1.34	1.91	80

C3 Anticoagulant Study Summary

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis
Lithium Heparin	14 Units/mL	Y = 0.966X + 0.28; r = 0.985
Sodium Heparin	14 Units/mL	Y = 0.979X – 0.95; r = 0.979
EDTA	1.5 mg/mL	Y = 0.855X + 5.27; r = 0.988

C4 Anticoagulant Study Summary

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis
Lithium Heparin	14 Units/mL	Y = 0.899X + 1.21; r = 0.978
Sodium Heparin	14 Units/mL	Y = 0.900X + 0.76; r = 0.992
EDTA	1.5 mg/mL	Y = 0.967X + 0.34; r = 0.985

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 7 2003

Ms. Kim Walker
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Brea, California 92822-8000

Re: k032035
Trade/Device Name: SYNCHRON LX® Systems Complement C3 Reagent, Complement C4 Reagent and LX Calibrator 1
Regulation Number: 21 CFR § 866.5240
Regulation Name: Complement components immunological test system
Regulatory Class: II
Product Code: CZW, DBI, JIT
Dated: June 30, 2003
Received: July 2, 2003

Dear Ms. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032035

Device Name: **SYNCHRON LX® Systems**
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and LX Calibrator 1

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The Beckman Coulter SYNCHRON LX® Systems Calibrator 1 (CAL 1), used in conjunction with SYNCHRON LX reagents, is intended for the calibration of the immunoprotein tests on SYNCHRON LX Systems.

J. Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032035

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)