K021572

JUL 19 2002

510(k) Summary
SYNCHRON® Systems
C-Reactive Protein (C-RP) Reagent and Calibrator

1.0 **Submitted By:**

Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 **Date Submitted:**

May 13, 2002

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems C-Reactive Protein (C-RP) Reagent
SYNCHRON Systems CX® C-RP Calibrator

3.2 **Classification Name**
C-Reactive Protein immunological test system (21 CFR § 866.5270)
Primary Calibrator (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems C-RP Reagent	SYNCHRON LX® Systems CRPH Reagent	Beckman Coulter, Inc.*	K010597
SYNCHRON Systems CX® C-RP Calibrator	SYNCHRON Systems CRP Calibrator	Beckman Coulter, Inc.	K910535

*Beckman Coulter, Inc., Brea, CA

5.0 **Description:**

The SYNCHRON Systems C-RP reagent is designed for optimal performance on the SYNCHRON CX (CX4/4CE/4Δ/4PRO, CX5/5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and LX (LX20/PRO) Systems. The reagent kit contains two 200-test cartridges that are packaged separately from the associated calibrators.

6.0 **Intended Use:**

C-RP reagent, when used in conjunction with SYNCHRON CAL 5 Plus on SYNCHRON LX Systems and CX C-RP Calibrator on SYNCHRON CX Systems, is intended for use in the quantitative determination of human C-reactive protein in human serum and plasma samples on SYNCHRON Systems by rate turbidimetry. CX C-RP Calibrator, when used in conjunction with SYNCHRON Systems C-RP Reagent, is intended for the calibration of C-reactive protein test systems on SYNCHRON CX Systems.

7.0 Comparison to Predicate(s):

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

	Similarities	
C-RP Reagent	Intended Use	Same as Beckman Coulter SYNCHRON LX Systems High Sensitivity CRPH Reagent
	Use of Latex particle technology	
	Sample Type	
	Antibody source (mouse, goat)	
	Liquid-stable reagents	
	Differences	
	Detection Wavelength	C-RP: 600 nm CRPH: 910 nm
	Platform	C-RP: All CX and LX models CRPH: LX PRO models only
	Initial Measuring Range	C-RP: 0.20 to 25 mg/dL (CX) 0.10 to 25 mg/dL (LX) CRPH: 0.02 to 8 mg/dL
	Extended Measuring Range	C-RP: up to 50 mg/dL CRPH: up to 38 mg/dL
	Sensitivity	C-RP: 0.20 mg/dL (CX), 0.10 mg/dL (LX) CRPH: 0.02 mg/dL

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 Systems C-RP Method Comparison Study Results

Candidate Method	Platform	Slope	Intercept	R	n	Predicate Method
SYNCHRON Systems C-RP Reagent	CX	1.007	0.05	0.996	132	Beckman Coulter SYNCHRON LX Systems CRPH Assay
	LX	1.033	0.01	0.998	143	

SYNCHRON LX System C-RP Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.49	0.014	2.77	80
Level 2	5.40	0.063	1.17	80
Level 3	13.45	0.210	1.56	80
Level 4	23.99	0.598	2.49	80
Total Imprecision				
Level 1	0.49	0.017	3.45	80
Level 2	5.40	0.086	1.60	80
Level 3	13.45	0.287	2.13	80
Level 4	23.99	0.624	2.60	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard, W-104
P.O. Box 8000
Brea, California 92822-8000

JUL 19 2002

Re: k021572
Trade/Device Name: SYNCHRON® Systems C-Reactive Protein (C-RP) Reagent and Calibrator
Regulation Number: 21 CFR § 866.5270 and 21 CFR § 862.1150
Regulation Name: C-Reactive Protein Immunological Test System and Primary Calibrator
Regulatory Class: II
Product Code: DCN, JIS
Dated: May 13, 2002
Received: May 14, 2002

Dear Ms. Tang:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021572

Device Name: **SYNCHRON® Systems**
C-Reactive Protein (C-RP) Reagent and Calibrator

Indications for Use:

C-RP reagent, when used in conjunction with SYNCHRON CAL 5 Plus on SYNCHRON LX® Systems and CX® C-RP Calibrator on SYNCHRON CX® Systems, is intended for use in the quantitative determination of human C-reactive protein in human serum and plasma samples by rate turbidimetry. Measurement of C-reactive protein aids in evaluation of stress, trauma, infection, inflammation, and surgery.

CX C-RP Calibrator, when used in conjunction with SYNCHRON Systems C-Reactive Protein (C-RP) Reagent, is intended for the calibration of C-reactive protein test systems on SYNCHRON CX Systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J J Reeve for E. Altair

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021572

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96