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K974050

BECKMAN

NOV 24 1997

Summary of Safety & Effectiveness
SYNCHRON® Systems C-Reactive Protein (CRP) Reagent

1.0 Submitted By:

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2.0 Date Submitted:

October 23, 1997

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems C-Reactive Protein (CRP) Reagent

3.2 Classification Names

C-Reactive Protein immunological test system (21 CFR § 866.5270)

4.0 Predicate Device(s):

IMMAGE™ Immunochemistry System C-Reactive Protein (CRP) Reagent K963061

5.0 Description:

The SYNCHRON Systems C-Reactive Protein (CRP) Reagent is designed for optimal performance on Beckman's SYNCHRON® Systems. It is intended for use in the quantitative determination of human C-reactive protein by rate nephelometry.

6.0 Intended Use:

The SYNCHRON® Systems C-Reactive Protein (CRP) Reagent , in conjunction with the SYNCHRON CX® CRP Calibrator Set, is intended for the quantitative determination of C-reactive protein concentration in serum or plasma.

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

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

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON Systems CRP Reagent	Sample types (serum/plasma)	Same as IMMAGE System CRP Reagent
	Shelf-life of 24 months (stored at 2-8°C)	Same as IMMAGE System CRP Reagent
	Antibody	Same as IMMAGE System CRP Reagent
DIFFERENCES		
SYNCHRON Systems CRP Reagent	Calibrator	The SYNCHRON uses a five level system calibration while the IMMAGE uses a single cal point update.
SYNCHRON Systems CRP Reagent	Methodology	The SYNCHRON Systems CRP utilizes a turbidimetric method while the IMMAGE System CRP utilizes a nephelometric method.

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.

Method Comparison for CRP Reagent

Candidate	Slope	Intercept	r	n	Predicate Method
SYNCHRON CRP Reagent	1.016	-0.10	0.999	60	IMMAGE CRP Reagent

Serum vs Plasma Study Summary

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis (mg/dL)
Lithium Heparin	14 Units/mL	Y = 1.042X - 0.45; r = 0.977
Sodium Heparin	14 Units/mL	Y = 0.994X - 0.07; r = 0.989
EDTA	1.5 mg/mL	Y = 0.992X - 0.20; r = 0.967

Estimated SYNCHRON CRP Reagent Imprecision

Sample	Mean (IU/mL)	S.D. (IU/mL)	%C.V.	N
Within-Run Imprecision				
Level 1	1.03	0.05	4.46	80
Level 2	4.06	0.06	1.58	80
Level 3	7.09	0.08	1.14	80
Total Imprecision				
Level 1	1.03	0.06	5.49	80
Level 2	4.06	0.18	4.49	80
Level 3	7.09	0.25	3.56	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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Annette Hellie
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Beckman Instruments, Inc.
200 S. Kraemer Boulevard, W-337
Brea, California 92822-8000

NOV 24 1997

Re: K974050
Trade Name: SYNCHRON® System C-Reactive Protein (CRP) Reagent
Regulatory Class: II
Product Code: DCK
Dated: October 23, 1997
Received: October 24, 1997

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K974050

Device Name: **SYNCHRON® Systems C-Reactive Protein (CRP) Reagent**

Indications for Use:

The SYNCHRON® Systems C-Reactive Protein (CRP) Reagent, in conjunction with the SYNCHRON CX® CRP Calibrator Set, is intended for the quantitative determination of C-reactive protein concentration in serum or plasma.

21 CFR 866.5270 C-reactive protein immunological test system.

(a) *Identification.* A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(b) *Classification.* Class II (performance standards)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maybem

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

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