K070626

Summary of Safety & Effectiveness
SYNCHRON® Systems
High Sensitivity Cardiac C-Reactive Protein (CRPH) Reagent

1.0 **Submitted By:**

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MAY - 4 2007

2.0 **Date Submitted:**

March 2, 2007

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems High Sensitivity Cardiac C-Reactive Protein (CRPH) Reagent

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

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number/ (Product Code)
Synchron Systems High Sensitivity Cardiac CRPH Reagent	Dade Behring CardioPhase hsCRP	Dade Behring Inc.*	K033908 (NQD)
Synchron Systems High Sensitivity Cardiac CRPH Reagent	Synchron Systems High Sensitivity CRPH Reagent	Beckman Coulter, Inc	K010597 (DCK)

*Dade Behring Inc. (Newark, DE)

5.0 **Description:**
High Sensitivity Cardiac C-Reactive Protein (CRPH) reagent, is intended for the quantitative determination of C-Reactive Protein in human serum or plasma by rate turbidimetry. SYNCHRON® System(s) CRPH reagent is based on the highly sensitive Near Infrared Particle Immunoassay rate methodology. An anti-CRP antibody-coated particle binds to CRP in the patient sample resulting in the formation of insoluble aggregates causing turbidity.

6.0 **Intended Use:**
High Sensitivity Cardiac C-Reactive Protein (CRPH) reagent, when used in conjunction with SYNCHRON LX®20 PRO System, UniCel® DxC 600/800 System(s) and SYNCHRON® Systems CAL 5 Plus, is intended for the quantitative determination of C-Reactive Protein in human serum or plasma by rate turbidimetry.

Clinical Significance:
Measurement of C-Reactive protein (CRP) aids in evaluation of stress, trauma, infection, inflammation, surgery, and associated diseases. Cardiac CRP assays are indicated for use as an aid in the identification and stratification of individuals at risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, CRP may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.

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	
Synchron Cardiac CRPH Reagent	Intended Use	Same as Dade Behring CardioPhase hsCRP
	Use of Latex particle technology	Same as Dade Behring CardioPhase hsCRP and Synchron CRPH
	Liquid stable reagent	The formulation is identical to LX System CRPH Reagent.
	Single point adjusted Calibration model	Same as LX System CRPH Reagent
	Differences	
Synchron Cardiac CRPH Reagent	Antibody source	SYNCHRON Cardiac CRPH uses goat and mouse while the Dade Behring Kit uses mouse only.
	Initial dilution range	SYNCHRON Cardiac CRPH initial dilution range covers from 0.02 to 8.0 mg/dL while the Dade Behring Kit covers from 0.31 to 20.0 mg/dL
	Extended dilution range	SYNCHRON Cardiac CRPH extended dilution range covers up to 38.0 mg/dL while the Dade Behring Kit covers uses multiple dilutions to cover the range from 0.016 to 1600.0 mg/dL
	Calibration model	SYNCHRON Cardiac CRPH uses a different model equation for the predetermined calibration curve than SYNCHRON CRPH.

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, linearity, and imprecision experiments.

Method Comparison Study Results

Analyte	Slope	Intercept	r	n	Predicate Method
Synchron Cardiac CRPH (0.2 to 80 mg/L)	1.048	0.024	0.9899	269	Behring CardioPhase hsCRP
Synchron Cardiac CRPH (0.2 to 10 mg/L)	1.030	-0.008	0.9910	149	Behring CardioPhase hsCRP

SYNCHRON High Sensitivity Cardiac CRPH Reagent Imprecision Results

Sample	**Mean (mg/dL)**	**S.D. (mg/dL)**	**%C.V.**	**N**
Within-Run Imprecision				
Level 1	0.063	0.0019	3.1	80
Level 2	1.368	0.0222	1.6	80
Level 3	5.639	0.0907	1.6	80
Total Imprecision				
Level 1	0.063	0.0033	5.3	80
Level 2	1.368	0.0381	2.8	80
Level 3	5.639	0.1823	3.2	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

Beckman Coulter, Inc.
c/o Ms. Tara Viviani
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MAY - 4 2007

Re: k070626
Trade/Device Name: Synchron® Systems High Sensitivity Cardiac C-Reactive Protein (CRPH) reagent
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system.
Regulatory Class: Class II
Product Code: NQD
Dated: March 2, 2007
Received: March 6, 2007

Dear Ms. Viviani:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070626

Device Name: **SYNCHRON® Systems**
High Sensitivity Cardiac C-Reactive Protein (CRPH) Reagent

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Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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