K07/002

Summary of Safety & Effectiveness
Immage® 800 Immunochemistry Systems
High Sensitivity Cardiac C-Reactive Protein (CCRP) Reagent

1.0 **Submitted By:**

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JUN 2 1 2007

2.0 **Date Submitted:**

April 6, 2007

3.0 **Device Name(s):**

3.1 **Proprietary Names**
Immage® Immunochemistry Systems High Sensitivity Cardiac C-Reactive Protein (CCRP) Reagent
Beckman CAL 5 Plus

3.2 **Classification Name**
C-Reactive Protein immunological test system (21 CFR § 866.5270)
Calibrator, multi-analyte mixture (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
IMMAGE Immunochemistry Systems High Sensitivity Cardiac CCRP Reagent	Dade Behring CardioPhase hsCRP	Dade Behring Inc.*	K033908
	IMMAGE Immunochemistry Systems High Sensitivity CRPH Reagent	Beckman Coulter, Inc	K010236
Beckman CAL 5 Plus	Beckman Cal 5 Plus	Beckman Coulter, Inc.	K926236/A

*Dade Behring Inc. (Newark, DE)

5.0 **Description:**

High Sensitivity Cardiac C-Reactive Protein (CCRP) reagent is intended for the quantitative determination of C-Reactive protein in human serum or plasma by rate turbidimetry. The IMMAGE® 800 Immunochemistry Systems CCRP 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. The rate of aggregate formation is directly proportional to the concentration of CRP in the sample.

CAL 5 Plus (Calibrator 5 Plus) is a frozen liquid serum matrix intended for use on IMMAGE® Immunochemistry Systems for the calibration of Anti-Streptolysin O (ASO), C-Reactive Protein (CRP) and Rheumatoid Factor (RF).

6.0 **Intended Use:**

High Sensitivity Cardiac C-Reactive Protein (CCRP) reagent, when used in conjunction with IMMAGE® 800 Immunochemistry Systems and Calibrator 5 Plus, is intended for the quantitative determination of C-Reactive protein in human serum or plasma by rate turbidimetry.

CAL 5 Plus (Calibrator 5 Plus), when used in conjunction with Beckman Coulter reagents, is intended for use on IMMAGE® Immunochemistry Systems for the calibration of Anti-Streptolysin O (ASO), C-Reactive Protein (CRP) and Rheumatoid Factor (RF).

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	
Immage Cardiac CCRP Reagent	Intended Use	Same as Behring CardioPhase hsCRP
	Use of Latex particle technology	Same as Dade Behring CardioPhase hsCRP and Immage CRPH
	Liquid stable reagent	The formulation is identical to Immage CRPH Reagent.
	Single point adjusted Calibration model	Same as IMMAGE CRPH Reagent
Beckman CAL 5 Plus	Formulation	Identical to Beckman CAL 5 Plus
	Differences	
Immage Cardiac CCRP Reagent	Antibody source	IMMAGE CCRP uses goat and mouse while the Dade Behring Kit uses mouse only.
	Initial dilution range	The IMMAGE initial dilution range covers from 0.2 to 60.0 mg/L while the Dade Behring Kit covers from 3.0 to 220 mg/L
	Extended dilution range	The IMMAGE extended dilution range covers up to 1440.0 mg/L while the Dade Behring Kit covers the range from 0.16 to 16000.0 mg/L
	Calibration model	IMMAGE High Sensitivity Cardiac CCRP uses a different model equation for the predetermined calibration curve than IMMAGE 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

Candidate	Slope	Intercept	R	N	Predicate Method
IMMAGE High Sensitivity Cardiac CCRP Reagent (0.2 to 60 mg/L)	0.965	0.334	0.9962	157	Dade Behring CardioPhase hsCRP
IMMAGE High Sensitivity Cardiac CCRP Reagent (0.2 to 10 mg/L)	1.013	-0.026	0.9939	98	Dade Behring CardioPhase hsCRP

IMMAGE High Sensitivity Cardiac CCRP Reagent Imprecision Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.807	0.0229	2.8	80
Level 2	13.56	0.4109	3.0	80
Level 3	51.538	1.7181	3.3	80
Total Imprecision				
Level 1	0.807	0.0279	3.5	80
Level 2	13.56	0.4248	3.1	80
Level 3	51.538	2.1933	4.3	80

Beckman CAL 5 Plus Stability Testing Summary

Stress Temperature	Duration of Incubation	Predicted Stability	Beckman Stability Claim*
32°C	40 days	32 months	24 months
37°C	24 days	33 months	24 months
41°C	15.5 days	32 months	24 months

* expiration dating placed on the packaging based in date of manufacture

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.
Diagnostics Development Center
c/o Ms. Tara Viviani
Sr. Regulatory Affair Specialist
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Brea, CA 92822-8000

JUN 21 2007

Re: k071002
Trade/Device Name: Immage® Immunochemistry Systems High Sensitivity Cardiac C-Reactive Protein (CCRP), Cal 5 Plus (Calibrator 5 Plus)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: NQD, JIX
Dated: April 06, 2007
Received: April 09, 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

510(k) Number (if known): K071002

Device Name: **Immage® Immunochemistry Systems**
High Sensitivity Cardiac C-Reactive Protein (CCRP)
Beckman CAL 5 Plus

Reagent:

Indications for Use:

High Sensitivity Cardiac C-Reactive Protein (CCRP) reagent, when used in conjunction with IMMAGE® 800 Immunochemistry Systems and Calibrator 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.

Calibrator:

Indications for use:

CAL 5 Plus (Calibrator 5 Plus), when used in conjunction with Beckman Coulter reagents, is intended for use on IMMAGE® Immunochemistry Systems for the calibration of Anti-Streptolysin O (ASO), C-Reactive Protein (CRP) and Rheumatoid Factor (RF).

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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K071002

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