

JUN 12 1998

**BECKMAN**

K981638

Summary of Safety & Effectiveness  
 IMAGE® Immunochemistry System C-Reactive Protein (CRP) Reagent

**1.0 Submitted By:**

Annette Hellie  
 Sr. Regulatory Specialist, Product Submissions  
 Beckman Coulter, Inc.  
 200 S. Kraemer Blvd., W-104  
 Brea, California 92822-8000  
 Telephone: (714) 993-8767  
 FAX: (714) 961-4123

**2.0 Date Submitted:**

May 7, 1998

**3.0 Device Name(s):****3.1 Proprietary Names**

IMAGE® Immunochemistry System C-Reactive Protein (CRP) Reagent

**3.2 Classification Name**

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

**4.0 Predicate Device(s):**

IMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMAGE System C-Reactive Protein (CRP) Reagent	Behring N Latex CRP	Behring Diagnostics*	K962523

\* Behring Diagnostics (Westwood, MA)

**5.0 Description:**

The IMAGE Immunochemistry System C-Reactive Protein (CRP) reagent, in conjunction with Calibrator 5 Plus, is intended for use in the quantitative determination of human C-reactive protein concentrations in human serum and plasma samples by rate nephelometry. This assay is designed for use with Beckman's IMAGE® Immunochemistry System.

**6.0 Intended Use:**

The IMAGE® Immunochemistry System C-Reactive Protein (CRP) reagent, in conjunction with Beckman Coulter IMAGE® Immunochemistry Systems and Calibrator 5 Plus, is intended for use in the quantitative determination of human C-reactive protein concentrations in human serum and plasma samples by rate nephelometry.

**Beckman Instruments, Inc.**

**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 System CRP Reagent	Intended Use	Same as Behring N Latex CRP
	Nephelometric methodology	
	Use of Latex particle technology	
DIFFERENCES		
IMMAGE System CRP Reagent	Form of reagent	the IMMAGE CRP is liquid stable while Behring N Latex CRP reagent is lyophilized
	Antibody source	IMMAGE CRP uses goat while Behring N Latex CRP uses rabbit.
	Stability	IMMAGE CRP is stable for 30 days once opened, properly stored while Behring N Latex CRP reagent is stable for one week following reconstitution,.

**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**  
 IMMAGE C-Reactive Protein (CRP) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE CRP Reagent	serum	0.953	-0.02	0.991	76	Behring N Latex CRP

**Estimated Imprecision**

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.35	0.039	11.1	80
Level 2	4.95	0.129	2.6	80
Level 3	6.69	0.236	3.5	80
Total Imprecision				
Level 1	0.35	0.043	12.1	80
Level 2	4.95	0.149	3.0	80
Level 3	6.69	0.266	4.0	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

JUN 12 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Annette Hellie  
Senior Regulatory Specialist,  
Product Submissions  
Beckman Coulter, Inc.  
200 S. Kraemer Boulevard, W-104  
Brëa, California 92822-8000

Re: K981638  
Trade Name: IMAGE® Immunochemistry System C-Reactive Protein  
(CRP) Reagent  
Regulatory Class: II  
Product Code: DCK  
Dated: May 7, 1998  
Received: May 8, 1998

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 (Pre-market 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.

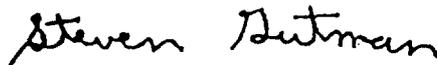
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 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): K981638

Device Name: **IMMAGE® Immunochemistry System  
C-Reactive Protein (CRP) Reagent**

Indications for Use:

The IMMAGE Immunochemistry System C-reactive protein (CRP) reagent, in conjunction with Beckman Coulter IMMAGE® Immunochemistry Systems and Calibrator 5 Plus, is intended for use in the quantitative determination of human C-reactive protein concentrations in human serum and plasma samples by rate nephelometry.

**Clinical Significance:**

Measurement of C-reactive protein aids in evaluation of stress, trauma, infection, inflammation, and surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K981638

Prescription Use                        
(per 21 CFR 801.109)

OR

Over-the-Counter Use                        
Optional Format 1-2-96