

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

K033908

**B. Analyte:**

CRP (high sensitivity)

**C. Type of Test:**

Quantitative

**D. Applicant:**

Dade Behring, Inc.

**E. Proprietary and Established Names:**

N *High Sensitivity* CRP

**F. Regulatory Information:**

1. Regulation section:

21 CFR 866.5270

2. Classification:

Class II

3. Product Code:

NQD

4. Panel:

82 Immunology

**G. Intended Use:**

1. Intended use(s):

N *High Sensitivity* CRP is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in human serum, and heparin and EDTA plasma by means of particle enhanced immunonephelometry using BN Systems.

2. Indication(s) for use:

In acute phase response, increased levels of a number of plasma proteins including C-reactive protein, is observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

3. Special condition for use statement(s):

None

4. Special instrument Requirements:

BN Systems (nephelometry)

**H. Device Description:**

The Dade N *High Sensitivity* CRP is an immunonephelometric assay. Polystyrene particles coated with monoclonal antibodies to CRP are agglutinated when mixed with samples containing CRP. The intensity of the scattered light in the nephelometer depends on the CRP content of the sample and therefore the CRP concentration can be determined versus dilutions of a standard of a known concentration. Results are reported in mg/L.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
N *High Sensitivity* CRP
2. Predicate K number(s):  
K991385
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen type	Serum, heparin- or EDTA plasma	Same
Instrumentation	BN Systems	Same
Precision	Same	Same
Sensitivity	Same	Same
Performance	Same	Same
Differences		
Item	Device	Predicate
Intended use	Cardiac risk assessment and injury/inflammation	Injury/inflammation

**J. Standard/Guidance Document Referenced (if applicable):**

AHA/CDC Scientific Statement (Circulation, 2003; 107:499-511)

**K. Test Principle:**

Immunonephelometry

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. *Precision/Reproducibility:*  
By reference to K991385
  - b. *Linearity/assay reportable range:*  
By reference to K991385
  - c. *Traceability (controls, calibrators, or method):*  
CRM 470
  - d. *Detection limit:*  
By reference to K991385
  - e. *Analytical specificity:*  
By reference to K991385
  - f. *Assay cut-off:*  
By reference to K991385
2. Comparison studies:
  - a. *Method comparison with predicate device:*  
N/A. Device is the same as predicate but seeks new claim.

- b. Matrix comparison:*  
By reference to K991385

3. Clinical studies:

- a. Clinical sensitivity:*  
N/A
- b. Clinical specificity:*  
N/A
- c. Other clinical supportive data (when a and b are not applicable):*  
Substantial peer-reviewed literature using the Dade test was provided to support clinical cardiac claims. A recent AHA/CDC expert panel recommendation statement using evidence-based processes concluded that cardiac claims were appropriate

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Relative risk/average hsCRP:

Low <1 mg/L

Average 1.0-3.0 mg/L

High >3.0 mg/L

**M. Conclusion:**

This device is substantially equivalent to K991385 N High Sensitivity CRP with an additional cardiac risk assessment claim supported by peer-reviewed literature and professional statements.