JAN 2 2 2004

510(k) Summary for
N *High Sensitivity* CRP

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033908

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Kathleen Dray-Lyons Tel: 781.826.4551
Preparation date:	January 20, 2004

2. Device Name/ Classification:

N *High Sensitivity* CRP:	C-reactive protein (CRP) immunological test system, Class II (866.5270)
Product Code:	81 NQD

3. Identification of the Legally Marketed Device:

N *High Sensitivity* CRP – K991385

4. Device Description:

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. The method is standardized against the IFCC/BCR/CAP reference preparation (Lot No.91/0619 = CRM 470 = RPPHS 91/0619 [Lot 5]).

5. **Device Intended Use:**

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. 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.

6. **Medical device to which equivalence is claimed and comparison information:**

The current N *High Sensitivity* CRP assay is an *in vitro* diagnostic test 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, which was cleared by FDA under 510(k) Premarket Notifications K962523 and K991385. Dade Behring is currently modifying the intended use statement and indications for use statements to include the use of CRP measurements as an aid in the identification of individuals at risk from cardiovascular disease. Patients with stable coronary disease or acute coronary syndromes, high sensitivity CRP (hsCRP) measurements may be useful as an independent marker of prognosis for recurrent events. This revision was accomplished without changing the current operating principle or reagent composition. The modified N *High Sensitivity* CRP assay is substantially equivalent in intended use and results obtained to the currently marketed N *High Sensitivity* CRP assay (K991385).

7. **Device Performance Characteristics:**

All performance characteristics were previously established under 510(k) Premarket Notification K991385.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 2 2004

Ms. Kathleen A. Dray-Lyons
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Business Community
P.O. Box 6101 – M.S. 514
Newark, DE 19714

Re: k033908
Trade/Device Name: N *High Sensitivity* CRP
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: NQD
Dated: December 15, 2003
Received: December 17, 2003

Dear Ms. Dray-Lyons:

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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 Statement

Device Name: N *High Sensitivity* CRP

Indications for Use:

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. 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.

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033908

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)