DEC 0 6 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
High Sensitivity C-Reactive Protein (CRP) Method for ADVIA® IMS™

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

The assigned 510(k) number is: K012337

1. Intended Use

This *in vitro* method is intended to quantitatively measure C-reactive protein (CRP) in serum on the Bayer ADVIA IMS systems. Measurements of CRP are used in the evaluation and treatment of injuries to body tissues and in monitoring the progress of traumatic injuries, rheumatic fever and rheumatoid arthritis.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Dade/Behring N High Sensitivity CRP, K991385	OQIY 21	OQIK

3. Device / Method

Product Name	Reagent BAN	Calibrator BAN
ADVIA IMS CRP	03987289 (100 test) 02136137 (250 test)	02537697

A. Imprecision (normal range)

ADVIA IMS	
Level (mg/L)	Total CV (%)
16.5	2.9
31.7	2.1
47.5	3.1

Dade/Behring BN100	
Level (mg/L)	Total CV(%)
10	<5.7
25	<5.7
60	<5.7

Imprecision (high sensitivity range)

ADVIA IMS	
Level (mg/L)	Total CV (%)
0.25	11.2
0.52	5.3
1.21	2.5

Dade/Behring BN100	
Level (mg/L)	Total CV(%)
0.5	2.5
1.3	3.8

B. Correlation (Y=ADVIA IMS, X=Comparison system) for Normal and High Sensitivity Ranges

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/L)	R	Sample Range (mg/L)
Serum	BN100	165	Y=0.97X - 0.04	2.41	0.998	1.0 – 179.0
Serum	BN100	25	Y=0.90X - 0.08	0.11	0.997	0.2 – 5.1

C. Interfering Substances (normal range)

Interfering Substance	Interfering Sub. Conc. (mg/dL)	CRP Conc. (mg/L)	Effect (% change)
Bilirubin (unconjugated)	20	5.0	+6
Bilirubin (conjugated)	20	5.3	+6
Hemoglobin	500	5.4	+4
Lipids (Triglycerides)	1000	5.2	+2

Interfering Substances (high sensitivity range)

Interfering Substance	Interfering Sub. Conc. (mg/dL)	CRP Conc. (mg/L)	Effect (% change)
Bilirubin (unconjugated)	25	1.79	-7
Bilirubin (conjugated)	25	1.95	+1
Hemoglobin	500	1.94	0
Lipids (Triglycerides)	500	1.82	-6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 6 2001

Kenneth T. Edds, Ph. D.
Regulatory Affairs
Bayer Corporation
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k012337
Trade/Device Name: ADVIA IMS High Sensitivity C-Reactive Protein Assay
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: October 12, 2001
Received: October 16, 2001

Dear Dr. Edds:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

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: K012337

Device Name: ADVIA IMS High Sensitivity C-Reactive Protein Assay

Indications for Use:

The Bayer Advia IMS C-Reactive Protein (CRP) assay is an in vitro diagnostic device intended to measure C-Reactive Protein in human serum. Measurements of CRP are used in the evaluation and treatment on injuries to body tissues and in monitoring the progress of traumatic injuries, rheumatic fever and rheumatoid arthritis.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012337

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)