NOV - 9 1999

K992136

SUMMARY OF SAFETY AND EFFECTIVENESS

Aspartate Aminotransferase (AST) Method for the ADVIA™ IMS Systems

Listed below is a comparison of the performance of the Bayer ADVIA IMS Aspartate Aminotransferase (AST) method and a similar device that was granted clearance of substantial equivalence (Bayer CHEM® 1 AST method). The information was extracted from the Bayer ADVIA IMS AST method and Bayer CHEM 1 AST method sheet.

INTENDED USE

The Bayer ADVIA IMS Aspartate Aminotransferase (AST) assay is an *in-vitro* diagnostic device intended to measure AST in human serum or plasma. Such measurements are used in the diagnosis and treatment of certain liver diseases and heart diseases.

AST METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3722-23		T01-1631-53	
Analytical Range:	0 to 1000 U/L		0 to 1030 U/L	
Precision (Total):	mean (U/L)	% CV	mean (U/L)	% CV
	30	4.2	31	4.1
	63	2.4	231	2.1
	153	1.6	369	3.6

Regression Equation: (serum) **y = 0.99x – 2.8**

where:
y = ADVIA IMS
x = Chem 1
n = 66
r = 0.998
Sy.x = 16.9
range = 16 to 910 U/L

Regression Equation: (plasma qualification) **y = 0.975x + 0.7**

where:
y = plasma
x = serum
n = 53
r = 0.997
Sy.x = 0.77
range = 14 to 69 U/L

Gabriel J. Marcuz Jr.
6/22/99

Interference

	Interfering Substance Concentration	AST (U/L)	Effect % Change
Hemolysis (Hemoglobin)	500 mg/dL	90	59
Bilirubin (conjugated)	20 mg/dL	89	-3
Bilirubin (unconjugated)	25 mg/dL	88	0
Lipemia (Triglycerides)	500 mg/dL	96	3

Gabriel J. Muraca Jr

Date 6/22/99

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

SUMMARY OF SAFETY AND EFFECTIVENESS

Creatine Kinase (CK) Method for the ADVIA™ IMS Systems

Listed below is a comparison of the performance of the Bayer ADVIA IMS Creatine Kinase (CK) method and a similar device that was granted clearance of substantial equivalence (Bayer CHEM 1® CK method). The information was extracted from the Bayer ADVIA IMS CK method and Bayer CHEM 1 CK method sheet.

INTENDED USE

The Bayer ADVIA IMS Creatine Kinase (CK) assay is an *in-vitro* diagnostic device intended to measure CK in human serum or plasma. Such measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases.

CK METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3729-23		T01-1491-53	
Analytical Range:	0 to 2200 U/L		0 to 2200 U/L	
Precision (Total):	mean (U/L)	% CV	mean (U/L)	% CV
	97	1.9	142	2.0
	231	1.3	407	2.9
	562	1.3	457	2.3

Regression Equation: (serum) **y = 0.99x + 2.7**

where:
y = ADVIA IMS
x = Chem 1
n = 67
r = 0.999
Sy.x = 18.2
range = 4 to 1873 U/L

Regression Equation: (plasma qualification) **y = 1.01x - 0.3**

where:
y = plasma
x = serum
n = 60
r = 0.999
Sy.x = 2.8
range = 37 to 472 U/L

Gabriel J. Munaca Jr.
6/22/95

Interference

	Interfering Substance Concentration	CK (U/L)	Effect % Change
Hemoglobin	500 mg/dL	113	28
Bilirubin (conjugated)	20 mg/dL	112	-2
Bilirubin (unconjugated)	25 mg/dL	109	0
Lipemia (Triglycerides)	500 mg/dL	114	-4

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511 Benedict Avenue
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6/22/99

Date

SUMMARY OF SAFETY AND EFFECTIVENESS

Creatinine Method for the ADVIA™ IMS Systems

Listed below is a comparison of the performance of the Bayer ADVIA Creatinine method and a similar device that was granted clearance of substantial equivalence (Bayer Chem 1® Creatinine method). The information was extracted from the Bayer ADVIA IMS Creatinine method sheet.

INTENDED USE

The Bayer ADVIA IMS Creatinine assay is an *in-vitro* diagnostic device intended to measure Creatinine in human serum, plasma, or urine. Such measurements are used in the diagnosis, monitoring and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring urine analytes.

SERUM

CREATININE METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3730-46 Calibrators T03-1291-62		T01-1456-53 T03-1291-62	
Analytical Range:	0 to 30 mg/dL		0.3 to 29 mg/dL	
Imprecision (Total):	Mean (mg/dL)	% CV	mean (mg/dL)	% CV
Level 1	1.10	2.96	1.3	5.6
Level 2	2.82	2.99	9.0	2.3
Level 3	5.67	1.70	15.1	2.6

Correlation to existing system	
Regression Equation: y = 0.96x + 0.38	
where:	y = ADVIA IMS
	x = Chem 1
	n = 108 (54 samples in duplicate)
	r = 0.999
	Sy.x = .31
	range = 0.4 to 28.9 mg/dL

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6/22/99

Plasma Qualification	
Regression Equation: y=0.96X +0.05	
where:	y = plasma
	x = serum
	n = 119 (60 samples in duplicate)
	r = 0.98
	Sy.x = 0.03
	range = .69 to 1.55 mg/dL

Interference

	Interfering Substance Concentration	Creatinine Concentration	Effect % Change
Hemoglobin	1000 mg/dL	2.98 mg/dL	+7
Bilirubin (conjugated)	18.8 mg/dL	2.94 mg/dL	-8
Bilirubin (unconjugated)	25 mg/dL	3.02 mg/dL	-5
Lipemia (Triglycerides)	1000 mg/dL	3.08 mg/dL	-2

URINE

CREATININE METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3730-46 Calibrators T03-1291-62		T01-1456-53 T03-1291-62	
Analytical Range:	0 to 300 mg/dL		2.4 to 232 mg/dL (0.3 mg/dL to 29.0mg/dL for undiluted samples)	
Imprecision (Total):	Mean (mg/dL)	% CV	mean (mg/dL)	% CV
Level 1	63.80	2.89	31	3.5
Level 2	111.30	2.33	51	3.3
Level 3	155.0	2.13	119	4.1

Gabriel J Murray Jr.
6/22/99

Correlation to existing system	
Regression Equation: y = 1.01x - 0.06	
where:	y = ADVIA IMS
	x = Chem 1
	n = 102 (51 samples in duplicate)
	r = 0.998
	Sy.x = 4.01
	range = 7 to 352 mg/dL

Interference

	Interfering Substance Concentration	Creatinine Concentration	Effect % Change
Ascorbic Acid	220 mg/dL	60.36 mg/dL	<1%
Acetaminophen	60 mg/dL	52.97 mg/dL	<1%
Salicylic Acid	550 mg/dL	56.02 mg/dL	<1%

Gabriel J. Muraca Jr.

6/22/99

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

SUMMARY OF SAFETY AND EFFECTIVENESS

Phenobarbital Method for the Bayer ADVIA® IMS Systems

Listed below is a comparison of the performance between the Bayer ADVIA IMS Phenobarbital method and a similar device that was granted clearance of substantial equivalence (Technicon RA-1000 method). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA IMS Phenobarbital method sheet and the RA-1000 method sheet.

INTENDED USE

This in vitro method is intended to quantitatively measure phenobarbital in human serum on the Bayer ADVIA IMS systems. Measurements of phenobarbital are used to aid in the diagnosis and treatment of phenobarbital overdose, patient compliance and to monitor serum levels of phenobarbital to ensure appropriate therapy.

METHOD		**ADVIA IMS**	**RA-1000**
		Part No.	**Part No.**
	Reagents	B41-3760-41	T01-2952-01
	Calibrators	B46-4091-01	T03-2953-01
Minimum Det.		Conc. 0.49 µg/mL	0.9 µg/mL
Precision (Total)		4.8% @ 14.7 µg/mL 5.1% @ 24.9 µg/mL 3.4% @ 40.3 µg/mL	3.0% @ 9.0 µg/mL 2.6% @ 23.0 µg/mL 2.7% @ 44.0 µg/mL
Correlation		$y = 0.98x + 0.80$ where y = ADVIA IMS, x = RA-1000 n = 52 r = 0.992 Syx = 1.23 µg/mL	

Interferences

Interfering Substance	Interfering Substance Concentration	Phenobarbital Concentration, µg/mL	Effect, % Change
Bilirubin (unconjugated)	25 mg/dL	15.5	+2
Bilirubin (conjugated)	20 mg/dL	15.9	-2
Hemoglobin	600 mg/dL	19.7	-5
Lipemia (Triglycerides)	1000 mg/dL	19.6	-3

Gabriel J. Munaca, Jr.
6/22/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 9 1999

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corp.
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K992136
Trade Name: 4 Additional Assays for the Bayer ADVIA® Integrated Modular System (IMS)
Regulatory Class: II
Product Code: CIT, CGX, DLZ, JLB
Dated: September 3, 1999
Received: September 7, 1999

Dear Mr. Muraca:

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 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). 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 (Premarket 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 requirements, 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

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 (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 (if known): K992136

Device Name: Bayer ADVIA® Integrated Modular System (IMS)

Indications For Use:

The Bayer *ADVIA IMS* Asparate Aminotransferase (AST) assay is an *in vitro* diagnostic device intended to measure AST activity in human serum or plasma. Such measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

The Bayer *ADVIA IMS* Creatine Kinase (CK) assay is an *in vitro* diagnostic device intended to measure CK activity in human serum or plasma. Such measurements are used as an aid in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne's dystrophy.

The Bayer *ADVIA IMS* Creatinine assay is an *in vitro* diagnostic device intended to measure creatinine in human serum, plasma or urine. Such measurements are used as an aid in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring urine analytes.

The Bayer *ADVIA IMS* Phenobarbital assay is an *in vitro* diagnostic device intended to measure phenobarbital in human serum. Measurements of phenobarbital are used as an aid in the diagnosis and treatment of phenobarbital overdose and in monitoring therapeutic levels of phenobarbital to ensure appropriate therapy.

(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-Counter Use_____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992136