K983398

JAN 29 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

Alkaline Phosphatase (AMP) Method for the ADVIA IMS Systems

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

INTENDED USE

The Bayer ADVIA IMS alkaline phosphatase (ALP) assay is an *in-vitro* diagnostic device intended to measure ALP in human serum or plasma. Such measurements are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This diagnostic method is not intended for use on any other diagnostic system.

ALP(AMP) METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3718-23		T01-1459-53	
Analytical Range:	0 to 2800 U/L		0 to 2250 U/L	
Precision (Total):	mean (U/L)	% CV	mean (U/L)	% CV
	74	3.6	65	3.8
	160	2.9	263	3.3
	420	2.1	547	3.2

Regression Equation: (serum) **y = 0.96x + 2.0**

where:
y = ADVIA IMS
x = Chem 1
n = 74
r = 0.999
Sy.x = 11.2
range = 36 to 1599 U/L

Regression Equation: (plasma qualification) **y = 1.06x - 0.9**

09167

where:
y = plasma
x = serum
n = 59
r = 0.999
Sy.x = 0.93
range = 33 to 111 U/L

Interference

	Interfering Substance Concentration	ALP(AMP)	Effect % Change
Hemoglobin	500 mg/dL	97 U/L	9
Bilirubin (conjugated)	20 mg/dL	100 U/L	8
Bilirubin (unconjugated)	25 mg/dL	107 U/L	1
Lipemia (Triglycerides)	1000 mg/dL	110 U/L	3

Gabriel J. Muraca, Jr.

6/30/98

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

Date

000163

SUMMARY OF SAFETY AND EFFECTIVENESS

Calcium Method for the Bayer ADVIA Integrated Modular System (IMS)

Listed below is a comparison of the performance between the Bayer ADVIA IMS Calcium method and a similar device that was granted clearance of substantial equivalence (Technicon CHEM 1 Calcium method). The information used in the Summary of Safety and Effectiveness was extracted from the Bayer ADVIA IMS Calcium method sheet and the CHEM 1 Calcium method sheet.

INTENDED USE

This in vitro method is intended to quantitatively measure calcium in human serum and plasma on the Bayer ADVIA IMS. Measurements of calcium are used in the diagnosis, monitoring and treatment of a variety of diseases including parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

METHOD		**ADVIA IMS**	**CHEM 1**
Part No.	**Reagents**	B41-3725-25	T01-1614-01
	Calibrators	T03-1291-62	T03-1291-62
Analytical Range		0 to 14.0 mg/dL	1 to 15 mg/dL
Precision (Total)		1.1% @ 8.4 mg/dL 2.2% @ 10.4 mg/dL 0.9% @ 13.6 mg/dL	2.3% @ 8.4 mg/dL 2.5% @10.6 mg/dL 2.2% @ 13.4 mg/dL
Correlation		y=0.96-0.8 mg/dL where y=ADVIA IMS x=CHEM 1 n=48 r=0.996 Sy.x=0.01 mg/dL	

000169

Plasma/Serum Equivalence	Plasma	Serum	Difference
	8.4 mg/dL	8.4 mg/dL	0.00
Within-run CV	0.75%	0.73%	0.02%

Interfering Substances

Bilirubin (unconjugated) 25 mg/dL	1.1%	effect change @ 9.0 mg/dL Ca
Hemoglobin 1000 mg/dL	3.0%	effect change @ 8.9 mg/dL Ca
Triglycerides 500 mg/dL	3.0%	effect change @ 9.1 mg/dL Ca

Gabriel J. Muraca, Jr.

6/30/98

Date

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

SUMMARY OF SAFETY AND EFFECTIVENESS

Glucose Method for the ADVIA IMS Systems

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

INTENDED USE

The Bayer ADVIA IMS Glucose assay is an in vitro diagnostic device intended to measure glucose in human serum or plasma. Such measurements are used in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders, including diabetes mellitus and neonatal hypoglycemia. This diagnostic method is not intended for use on any other diagnostic system.

GLUCOSE METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Reagents B41-3732-26		T01-1460-53	
	Calibrators T03-1291-62		T03-1291-62	
Analytical Range:	0 to 800 mg/dL		0 to 675 mg/dL	
Precision (Total):	mean (mg/dL)	% CV	mean (mg/dL)	% CV
	48	3.66	87	2.7
	97	3.03	262	2.9
	293	1.80	305	2.3
			562	1.3

Regression Equation: (serum) **y = 1.03x + 0.71**

where:
- y = ADVIA IMS
- x = Chem 1
- n = 58
- r = 0.993
- Sy.x = 11.4
- range = 51 to 534 mg/dL

Regression Equation: (plasma qualification) **y = 0.97x + 4.12**

where:
- y = plasma
- x = serum
- n = 60
- r = 0.943
- Sy.x = 4.1
- range = 58 to 174 mg/dL

Interference

	Interfering Substance Concentration	Glucose Concentration	Effect % Change
Hemoglobin	1000 mg/dL	297 mg/dL	0.5
Bilirubin (conjugated)	25 mg/dL	288 mg/dL	0.5
Bilirubin (unconjugated)	25 mg/dL	271 mg/dL	1.3
Lipemia (Triglycerides)	500 mg/dL	274 mg/dL	9.5

Gabriel J. Muraca, Jr.

6/30/98

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

Date

SUMMARY OF SAFETY AND EFFECTIVENESS

Ferritin Method for Bayer ADVIA™ MODULAR SYSTEM

Listed below is a comparison of the performance between the ADVIA Ferritin method and a similar device that was granted clearance of substantial equivalence (Immuno 1 Ferritin assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA ferritin method sheet and the Immuno 1 ferritin method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure ferritin, an iron storage protein, in human serum using Bayer Immuno 1 ferritin reagents on a Bayer ADVIA Modular System. Measurements of ferritin are used in the diagnosis and treatment of iron deficiency or iron overload disease states.

METHOD	**Immuno 1 Ferritin** (predicate device)		**ADVIA Ferritin**	
Part No.	Reagents Calibrators	T01-2863-51 T03-3251-01	Reagents Calibrators	B42-3902-21 B43-3933-01
Minimum Detectable Conc.	0.3 ng/mL		0.06 ng/mL	
Precision (Total CV%)	21 ng/mL 148 ng/mL 344 ng/mL	7.1% 5.0% 5.0%	28 ng/mL 108 ng/mL 245 ng/mL	4.1% 4.8% 5.0%

Correlation $y = 1.040\ x - 6.132$

where

y =	Bayer ADVIA Modular System
x =	Bayer Immuno 1 System
n =	50
r =	0.993
S_{yx} =	57.50 ng/mL

000173

Interference

	Interfering Substance Concentration	Ferritin concentration	Ferritin (Neat concentration)	Effect % Change
Hemoglobin	1000 mg/dL	179.8 ng/mL	178.3 ng/mL	0.8
Bilirubin	27.5 mg/dL	34.74 ng/mL	36.01ng/mL	3.5
Urea Nitrogen	200 mg/dL	175.1 ng/mL	182.0 ng/ml	3.8
Lipemia (Triglycerides)	1110 mg/dL	212.6 ng/mL	222.6 ng/ml	4.5

Gabriel J. Muraca, Jr.

6/30/98

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

Date

SUMMARY OF SAFETY AND EFFECTIVENESS

hCG Assay for Bayer ADVIA® Integrated Modular System

Listed below is a comparison of the performance between the ADVIA hCG method and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1® hCG Assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA hCG insert and the Immuno 1® hCG Assay method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure hCG, human chorionic gonadotropin, in human serum using ADVIA hCG Assay on a *Bayer ADVIA®* Integrated Modular System. Measurements of hCG are used in the detection of pregnancy.

METHOD	**ADVIA hCG Assay**	**Immuno 1 hCG Assay** (predicate Device)
Part No.	Reagents B42-3907-43 Calibrators B43-3941-01	Reagents T01-2966-51 Calibrators T03-3148-01
Minimum Detectable Conc.	0.1 mIU/mL	0.5 mIU/mL
Precision (Total CV)	4.2% @ 12.1 mIU/mL 4.5% @ 23.9 mIU/mL 5.5% @ 198.1 mIU/mL	4.0% @ 18.3 mIU/mL 3.7% @ 55.7 mIU/mL 3.7% @ 198.1 mIU/mL
Correlation	$y = 0.99x + 1.96$ where y = ADVIA hCG Assay x = Immuno 1 hCG Assay n = 40 r = 1.0 S_{yx} = 17.5 mIU/mL	

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, mIU/mL		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	1.0 g/L	1000	17.2	16.8	-2.3
Lipids (Triglycerides)	11.3 mmol/L	1000	17.2	15.7	-8.7
Bilirubin	428 µmol/L	25	16.5	15.5	-6.1
Urea Nitrogen	71.4 mmol/L	200	17.2	15.9	-7.6

Gabriel J. Muraca, Jr.

6/30/98

Date

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

SUMMARY OF SAFETY AND EFFECTIVENESS

3rd Generation TSH Assay for Bayer ADVIA® Integrated Modular System

Listed below is a comparison of the performance between the ADVIA 3rd Generation TSH method and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1® TSH Assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA 3rd Generation TSH insert and the Immuno 1® TSH Assay method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure TSH, Thyroid Stimulating Hormone, in human serum using ADVIA 3rd Generation TSH Assay on a *Bayer ADVIA®* Integrated Modular System. Measurements of TSH are used in the diagnosis of thyroid or pituitary disorders. This assay allows the determination of TSH with 3rd generation sensitivity of less than 20% total coefficient of variation (CV) at 0.01 to 0.02 µIU/mL, as defined by the American Thyroid Association.

METHOD	**ADVIA TSH Assay**	**Immuno 1 TSH Assay** (predicate Device)
Part No.	Reagents B42-3921-43 Calibrators B43-3948-01	Reagents T01-2942-51 Calibrators T03-3568-01
Minimum Detectable Conc.	0.005 µIU/mL	0.03 µIU/mL
Precision (Total CV)	13.2% @ 0.02 µIU/mL 2.9% @ 0.52 µIU/mL 2.3% @ 4.95 µIU/mL 2.6% @ 31.10 µIU/mL	6.3% @ 1.3 µIU/mL 2.0% @ 9.0 µIU/mL 1.8% @ 22.5 µIU/mL
Correlation	y = 0.98x - 0.357 where y = ADVIA TSH Assay x = Immuno 1 TSH Assay n = 50 r = 0.997 S_{yx} = 1.48 µIU/mL	

000177

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, µIU/mL		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	1.0 g/L	1000	3.32	3.38	1.8
Lipids (Triglycerides)	11.3 mmol/L	1000	3.49	3.45	-0.9
Bilirubin	428 µmol/L	25	3.25	3.30	1.5
Urea Nitrogen	71.4 mmol/L	200	3.30	3.31	-1.5

Gabriel J. Muraca, Jr.

6/30/98

Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 29 1999

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

Re: K982328
Trade Name: Bayer ADVIA® IMS™ System
Regulatory Class: II
Product Code: CJO, CFR, CIC, CJO, DHA, JLW, JMG
Dated: November 12, 1998
Received: November 19, 1998

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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): K982328

Device Name: **Bayer ADVIA™ Integrated Module System (IMS™)**

Indications For Use:

ALKALINE PHOSPHATASE
(ALP)

Intended Use:
The Bayer ADVIA IMS alkaline phosphatase (ALP) assay is an *in vitro* diagnostic device intended to measure ALP in human serum or plasma. Such measurements are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This diagnostic method is not intended for use on any other diagnostic system.

CALCIUM
(CA)

Intended Use:
The Bayer ADVIA IMS Calcium assay is an *in vitro* diagnostic device intended to measure calcium in human serum or plasma. Measurements of calcium are used in the diagnosis, monitoring and treatment of a variety of diseases including parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany. This diagnostic method is not intended for use on any other diagnostic system.

GLUCOSE
(GLU)

Intended Use:
The Bayer ADVIA IMS Glucose assay is an *in vitro* diagnostic device intended to measure glucose in human serum or plasma. Such measurements are used in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders, including diabetes mellitus and neonatal hypoglycemia. This diagnostic method is not intended for use on any other diagnostic system.

(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)

006252

510(k) Number (if known): K980328

Device Name: **Bayer ADVIA™ Integrated Module System (IMS™)**

Indications For Use:

FERRITIN
(FERR)

Intended Use:
The Bayer ADVIA IMS Ferritin assay is an *in vitro* diagnostic device intended to quantitatively measure ferritin (an iron-storage protein) in human serum. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency. This diagnostic method is not intended for use on any other diagnostic system.

HUMAN CHORIONIC GONDADOTROPIN
(hCG)

Intended Use:
The Bayer ADVIA IMS hCG assay is an *in vitro* diagnostic device intended to quantitatively measure total beta (β) in human chorionic gonadotropin (hcG) in human serum. Measurements of human chorionic gonadotropin are used in the detection of pregnancy. This diagnostic method is not intended for use on any other diagnostic system.

THYROID STIMULATING HORMONE
(TSH)

Intended Use:
The Bayer ADVIA IMS TSH assay is an *in vitro* diagnostic device intended to quantitatively measure thyroid stimulating hormone (TSH)in human serum. This assay allows the determination of TSH with 3rd generation sensitivity of less than 20% total coefficient variation (CV) at 0.01 to 0.02 mIU/L or µiU/mL, as defined by the American Thyroid Association. Measurements thyroid stimulating hormone are used in the diagnosis of thyroid or pituitary disorders. This diagnostic method is not intended for use on any other diagnostic system.

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

Joseph C. Boone
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 1/28/99

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

000253 Optional Format 1-2-96)