SEP 15 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Albumin 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: K992399

1. Intended Use

This *in vitro* diagnostic method is intended to measure albumin in human serum or plasma on the Bayer ADVIA IMS system. Measurements of albumin are used in the diagnosis, monitoring and treatment of a variety of diseases involving the liver and kidneys.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Technicon CHEM 1® Albumin	T01-1458-53	T03-1291-62

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IM Albumin	B41-3717-26	T03-1291-62

A. Imprecision(SERUM)

ADVIA IMS	
Level (g/dL)	Total CV(%)
2.1	1.9
3.4	1.6
4.9	1.5

CHEM 1	
Level (g/dL)	Total CV(%)
2.4	25
3.7	2.4
6.6	2.1

Correlation (Y=ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (g/dL)	r	Sample Range (g/dL)
Serum	CHEM 1+	53	Y=1.01X+0.55	0.13	0.990	1.4 – 5.3
Plasma(y), Serum(x)	ADVIA IMS	59	Y=0.96X+0.12	0.06	0.978	3.9 – 5.2

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Albumin Conc. (g/dL)	Effect (% change)
U. Bilirubin	25	4.2	-4.8
Hemoglobin	1000	3.5	+5.7
Lipids (Triglycerides)	1000	3.5	-2.9

7/16/99
Gabriel J. Marra Jr.
Manager Reg Affairs

Analytical Range

Serum/Plasma: 1 to 6 g/dL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
T.Bilirubin 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: _____

1. Intended Use

This *in vitro* method is intended to quantitatively measure total bilirubin in human serum and plasma on the Bayer ADVIA IMS systems. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disorders.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Technicon CHEM 1® T.Bilirubin	T01-1522-53	T03-1291-62

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS T.Bilirubin	B41-3723-46	T03-1291-62

A. Imprecision(SERUM)

ADVIA IMS	
Level (mg/dL)	Total CV(%)
1.1	7.0
4.5	5.1
17.0	2.4

CHEM 1	
Level (mg/dL)	Total CV(%)
1.1	9.1
5.0	4.8
20.0	2.6

Correlation (Y=ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	r	Sample Range (mg/dL)
Serum	CHEM 1+	58	Y=1.08X-0.11	0.26	0.998	0.2 – 26.1
Plasma(y), Serum(x)	ADVIA IMS	57	Y=1.01X-0.01	0.02	0.994	0.16 – 0.92

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Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	T.Bilirubin Conc. (mg/dL)	Effect (% change)
Hemoglobin	500	6.9	+1
Lipids (Triglycerides)	500	6.7	-34

Analytical Range

Serum/Plasma: 0 to 45 mg/dL

SUMMARY OF SAFETY AND EFFECTIVENESS

CO2 Method for the Bayer ADVIA Integrated Modular System (IMS)

Listed below is a comparison of the performance between the Bayer ADVIA IMS CO2 method and a similar device that was granted clearance of substantial equivalence (Technicon CHEM 1 Carbon Dioxide, Enzymatic). The information used in the Summary of Safety and Effectiveness was extracted from the Bayer ADVIA IMS CO2 method sheet and the CHEM 1 CO2 (Enzymztic) method sheet.

INTENDED USE

This *in-vitro* diagnostic method is intended to measure carbon dioxide (CO_2) in human serum. Measurement of CO_2 is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

METHOD		**ADVIA IMS**	**CHEM 1**
Part No.	**Reagents**	B41-3726-43	T01-3253-53
	Calibrators/	T03-1291-62/	T01-1291-62/
	CO2 diluent	T23-1291-52	T23-1291-52
Analytical Range		10 to 40 mEq/L	10 to 40 mEq/L
Precision (Total)		5.3% @ 11.98 mEq/L 4.3% @ 19.10 mEq/L 3.0% @ 28.39 mEq/L	4.5% @ 14 mEq/L 3.8% @ 22 mEq/L 3.3% @ 28 mEq/L
Correlation		Y=0.99X+0.41 mEq/L Where Y=ADVIA IMS X=CHEM 1 N=106 (53 pairs) r=0.993 Sy.x=0.999 mEq/L	

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Interfering Substances

Bilirubin (unconjugated) 25 mg/dL	0.0% effect change @ 28.42 mEq/L CO2
Bilirubin (conjugated) 25 mg/dL	-2.0% effect change @ 27.84 mEq/L CO2
Hemoglobin (hemolysate) 500 mg/dL	-37% effect change @ 28.83 mEq/L CO2
Lipemia (Triglycerides) 500 mg/dL	-10.0% effect change @ 28.67 mEq/L CO2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Digoxin 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: _____ (leave blank)

1. **Intended Use**
   This in vitro method is intended to quantitatively measure digoxin in human serum on the Bayer ADVIA IMS systems. Measurements of digoxin are used to aid in attaining optimum therapy in patients treated with the drug.

2. **Predicate Device**

Product Name	Reagent Part #	Calibrator Part #
Bayer Immuno 1 Digoxin	T01-2875-51	T01-2864-01

3. **Device / Method**

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS Digoxin	B41-3757-42	B46-4119-01

A. Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV (%)
0.82	6.8
1.80	-5.1
3.81	4.8

Immuno 1	
Level (ng/mL)	Total CV(%)
0.7	8.2
2.2	4.2
3.4	3.6

B. Correlation (Y=ADVIA IMS, X=Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	63	Y=0.93X – 0.11	0.17	0.98	0.15-3.90

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C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Digoxin Conc. (ng/mL)	Effect (% change)
Bilirubin	25	2	3.9
Bilirubin (unconjugated)	25	2	-3.9
Hemoglobin	500	2	-0.3
Lipids (Triglycerides)	500	2	-11.7

Analytical Range: 0.1-5.0 ng/mL
Minimum Detectable Concentration: 0.1 ng/mL

Date 7/16/99

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.
Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
914-524-3494 (fax 914-524-2500)

Gabriel J. Muraca Jr.

SUMMARY OF SAFETY AND EFFECTIVENESS

HDL cholesterol Method for the ADVIA IMS Systems

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

INTENDED USE

The Bayer ADVIA IMS HDL cholesterol assay is an *in-vitro* diagnostic device intended to measure HDL cholesterol in human serum and plasma. Such measurements are used in the diagnosis, monitoring and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This diagnostic method is not intended for use on any other diagnostic system.

SERUM

HDL CHOLESTEROL METHOD:	**ADVIA IMS**		**CHEM 1**	
Part Number:	Cholesterol Reagent B41-3727-46 HDL precipitating reagent B21-3733-01 Calibrators T03-1291-62		cholesterol reagent T01-2869-01 HDL Precipitating reagent T01-1897-56 Calibrators T03-1291-62	
Analytical Range:	0 to 250 mg/dL		10 to 100 mg/dL	
Precision (Total):	Mean (mg/dL)	% CV	mean (mg/dL)	% CV
Level 1	18	3.2	20	8.5
Level 2	42	2.6	46	6.7
Level 3	121	2.8	58	4.8

Correlation to existing system	
Regression Equation: y = 0.997x + 1.95	
where:	y = ADVIA IMS
	x = Chem 1
	n = 107 (54 samples in duplicate)
	r = 0.987
	Sy.x = 3.58
	range = 19 to 123 mg/dL

7/16/94 Gabriel J Munaco Jr - Manager Reg. Affairs.

Plasma Qualification		
Regression Equation: y=0.995X +0.12		
where:	y	= plasma
	x	= serum
	n	= 90 (47 samples in duplicate)
	r	= 0.996
	Sy.x	= 1.3
	range	= 18 to 71 mg/dL

Interference

	Interfering Substance Concentration	HDL cholesterol Concentration	Effect % Change
Hemoglobin	250 mg/dL	47.2 mg/dL	-19
Bilirubin (conjugated)	6.25 mg/dL	45.2 mg/dL	-27
Bilirubin (unconjugated)	25 mg/dL	43.1 mg/dL	-2
Lipemia (Triglycerides)	1000 mg/dL	44.3 mg/dL	+1

Gabriel J. Muraca, Jr. 7/16/98

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

Date

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Inorganic Phosphorus 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: _____

1. Intended Use

This *in vitro* diagnostic method is intended to measure Inorganic Phosphorus in human serum, plasma or urine on the Bayer ADVIA IMS system. . Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Technicon CHEM 1® Inorganic Phosphorus	T01-1609-53	T03-1291-62

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS Inorganic Phosphorus	B41-3734-46	T03-1291-62

A. Imprecision(SERUM)

ADVIA IMS	
Level (mg/dL)	Total CV(%)
2.5	1.7
5.0	2.1
8.8	2.7

CHEM 1	
Level (mg/dL)	Total CV(%)
3.1	3.4
6.6	2.7
7.7	2.8

B. Imprecision(URINE)

ADVIA IMS	
Level (mg/dL)	Total CV(%)
24.8	1.9
69.8	2.2
96.3	1.9

CHEM 1	
Level (mg/dL)	Total CV(%)
37	2.6
55	2.7

Correlation (Y=ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	r	Sample Range (mg/dL)
Serum	CHEM 1+	50	Y = 0.94X + 0.15	0.15	0.997	1.3 – 10.0 mg/dL
Plasma(y), Serum(x)	ADVIA IMS	58	Y=0.96X-0.17	0.12	0.977	1.9-4.4 mg/dL
Urine	CHEM 1	48	Y = 1.01X + 0.15	1.17	0.999	4.5 – 99.9 mg/dL

Gabriel J. Monaco Jr. - Manager Reg Affairs.
7/16/99

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Inorganic Phosphorus Conc. (mg/dL)	Effect (% change)
Bilirubin	20	3.7	+2.2
Hemoglobin	500	3.6	+19.4
Lipids (Triglycerides)	500	3.8	+21.6
Acetaminophen	50	8.0	-3.8
Ascorbic Acid	200	18.4	+1.3
Salicylate	500	18.4	+5.0

Analytical Range

Serum/Plasma: 0 to 15 mg/dL
Urine: 0 to 100 mg/dL

Gabriel J. Murray Jr.
7/16/99

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Sodium, Potassium, and Chloride ISE methods 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: _____

1. Intended Use

This *in vitro* diagnostic method is intended to measure Sodium (Na), Potassium (K) and Chloride (Cl) in human serum, plasma on the Bayer ADVIA IMS system

2. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS Sodium, Potassium, Chloride	B48-4054-54	T21-4055-01 (Hi) T21-4056-01 (Lo)

Imprecision

ANALYTE	Level (mmol/L)	Total CV(%)
Sodium	113 139	1.0 1.0
Potassium	3.4 5.9	1.3 1.2
Chloride	93 113	1.2 1.2

Correlation (Y=ADVIA IMS, X=comparison system)

ANALYTE (Serum)	Comparison System (X)	N	Regression Equation	Syx (mmol/L)	R	Sample Range (mmol/L)
Sodium	IL Flame	53	0.94 x Flame + 7.08 mmol/L	1.68	0.957	120.0-147.1
Potassium	IL Flame	54	1.03 x Flame – 0.15 mmol/L	0.17	0.990	2.55-8.72
Chloride	Chloridometer	51	0.84 x Chloridometer + 16.0 mmol/L	1.1	0.986	83.6-115.5

Plasma/Serum Comparison

	Sodium	Potassium	Chloride
Mean Serum Level	137.2	3.97	105.2
Mean Plasma Level	137.2	3.76	105.2
Mean Difference	0.0	0.21	0.0
% Difference	0.0	5.6	0.0

Gabriel J. Muraca Jr.

G. J. Muraca Jr.
Manager RA
Bayer Corporation

7/16/99
Date

Interfering Substances

Sodium: No significant effect on serum has been demonstrated from bromide, ammonium and iodide.

Potassium: Since the concentration of potassium inside erythrocytes is much greater than that in extracellular fluid, hemolysis should be avoided, and the serum/plasma should be separated from the cells as soon as possible after collection.

Chloride: Sodium Salicylate at a level of 2.2 mmol/L (30 mg/dL) will elevate the chloride result by less than 2.0 mmol/L. The presence of bromide or iodide salts will falsely elevate chloride results.

Analytical Range

Serum or Plasma:

Sodium	40 to 205 mmol/L
Potassium	1.5 to 15 mmol/L
Chloride	50 to 200 mmol/L

Gabriel J. Munaca, Jr.
7/16/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 15 1999

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

Re: K992399
Trade Name: 9 Additional IMS Assays for the Bayer ADVIA® IMS™ System
Regulatory Class: II
Product Code: CIX, CIG, CHS, KXT, CHH, CEO JGS, CEM, CGZ
Dated: July 16, 1999
Received: July 19, 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 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):

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

Indications For Use:

The *Bayer ADVIA IMS Albumin* assay is an *in vitro* diagnostic device intended to measure *Albumin* in human serum or plasma. Measurements of albumin are used in the diagnosis, monitoring and treatment of a variety of diseases involving the liver and kidney.

The *Bayer ADVIA IMS Total Bilirubin* assay is an *in vitro* diagnostic device intended to measure bilirubin in human serum or plasma. Measurements of direct or total bilirubin, organic compounds formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis, monitoring and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disorders.

The *Bayer ADVIA IMS Carbon Dioxide (CO2)* assay is an *in vitro* diagnostic method intended to measure *CO2* in human serum. Measurements of CO2 are used as an aid in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

The *Bayer ADVIA IMS Digoxin* assay is an *in vitro* diagnostic device intended to measure *Digoxin,* a cardioactive drug, in human serum.. Measurements of Digoxin are used as an aid in the diagnosis of Digoxin overdose and in the monitoring therapeutic levels of Digoxin 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)

(Division Sign-Off)
Division of Clinical L
510(k) Number k992395

(Optional Format 1-2-96)

510(k) Number (if known):

Device Name: **Bayer ADVIA® Integrated Modular System IMS**

Indications For Use:

The *Bayer ADVIA IMS HDL Cholesterol* assay is an *in vitro* diagnostic device intended to measure *HDL Cholesterol* (a lipoprotein) in human serum and plasma. Such measurements are used as an aid in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

The *Bayer ADVIA IMS Inorganic Phosphorus* assay is an *in vitro* diagnostic device intended to measure p*hosphorus* in human serum, plasma or urine. Measurements of inorganic phosphorus are used in the diagnosis, monitoring and treatment of a variety of diseases involving the parathyroid gland and kidney, and vitamin D imbalance.

The *Bayer ADVIA IMS Ion Selective Electrode* assays for Sodium, Potassium, and Chloride are *in vitro* diagnostic devices intended to measure these analytes in human serum or plasma. Measurements of sodium are used as an aid in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Measurements of potassium are used as an aid in the diagnosis and treatment of renal tubular disease, hyperaldosteronism, metabolic alkolosis, adrenocortical disease and diabetic ketoacidosis. Measurements of chloride are used as an aid in the diagnosis and treatment of acid-base and water imbalance. It is especially important to measure chloride during the correction of hypokalemic alkalosis and also during severe, prolonged vomiting which lowers serum chloride levels.

(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)