JUL 2 2 1999

K991817

SUMMARY OF SAFETY AND EFFECTIVENESS

Amylase (AMY) Method for the ADVIA IMS Systems

Listed below is a comparison of the performance of the Bayer ADVIA Amylase (AMY) method and a similar device that was granted clearance of substantial equivalence (Bayer RA-XT Amylase method). The information was extracted from the Bayer ADVIA AMY method and Bayer RA-XT Amylase method sheet.

INTENDED USE

The Bayer ADVIA IMS Amylase (AMY) assay is an *in-vitro* diagnostic device intended to measure AMY in human serum, plasma or urine. Such measurements are used in the diagnosis and treatment of acute pancreatitis. This diagnostic method is not intended for use on any other diagnostic system.

AMY METHOD:	**ADVIA IMS**		**RA-XT**	
Part Number:	Reagents B41-3721-23		T01-3508-01	
Analytical Range:	0 to 1500 U/L		10 to 3400 U/L	
Precision (Total):	mean (U/L)	% CV	mean (U/L)	% CV
	56	2.5	51	2.2
	113	2.1	179	1.0
	430	1.5	373	0.6

Regression Equation: (serum) **y = 1.01x –5.7**

where:
y = ADVIA IMS
x = RA-XT
n = 72
r = 0.999
Sy.x = 11.9
range = 19 to 1318 U/L

Regression Equation: (plasma qualification) **y = 1.00x - 0.2**

where:
y = plasma
x = serum
n = 60
r = 0.999
Sy.x = 1.0
range = 18 to 106 U/L

Gabriel J. Munoz, Jr.
Manager RA
5/21/99

Interference

	Interfering Substance Concentration	AMY (U/L)	Effect % Change
Hemolysis (Hemoglobin)	500 mg/dL	112	+2
Bilirubin (conjugated)	20 mg/dL	113	-4
Bilirubin (unconjugated)	25 mg/dL	112	-2
Lipemia (Triglycerides)	500 mg/dL	113	3

Urine Samples:

AMY METHOD:	**ADVIA IMS**		**RA-XT**	
Part Number:	Reagents B41-3721-23		T01-3508-01	
Analytical Range:	0 to 1500 U/L		10 to 3400 U/L	
Precision (Total):	mean (U/L)	% CV	mean (U/L)	% CV
	50	1.3	57	3.4
	218	1.1	172	1.3
	493	1.6	510	1.3

Regression Equation: (urine) **y = 0.97x –4.7**

where:
y = ADVIA IMS
x = RA-XT
n = 72
r = 0.999
Sy.x = 9.7
range = 17 to 1465 U/L

Interference

	Interfering Substance Concentration	AMY (U/L)	Effect % Change
Ascorbic Acid	400 mg/dL	115	1
Acetaminophen	50 mg/dL	116	-1
Salicylate	500 mg/dL	116	-2

JJM, Jr. RA
6/21/99

SUMMARY OF SAFETY AND EFFECTIVENESS

Cortisol Method for Bayer ADVIA® IMS™

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

INTENDED USED

This *in vitro* method is intended to quantitatively measure cortisol, a hormone secreted by the human adrenal gland, in human serum using Bayer cortisol reagents on a Bayer ADVIA Modular System. Measurements of cortisol are used as a direct indicator of adrenal status or an indirect monitor of pituitary function.

METHOD	**Immuno 1 Cortisol** (predicate device)		**ADVIA Cortisol**	
Part No.	Reagents T01-2910-01 Calibrators T03-3252-01		Reagents Calibrators	B42-3899-21 B43-3931-01
Minimum Detectable Conc.	0.2 µg/dL		0.1 µg/dL	
Precision (Total CV%)	3.2 µg/dL 20.1 µg/dL 33.3 µg/dL	7.9% 4.5% 4.7%	4.4 µg/dL 17.3 µg/dL 37.5 µg/dL	6.0% 5.0% 3.8%
Correlation	$y = 1.013 x - 0.142$ where y = Bayer ADVIA Modular System x = Bayer Immuno 1 System n = 57 r = 0.996 S_{yx} = 0.961 µg/dL			

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration		Effect
	SI Units	(mg/dL)	(nmol/L)	(µg/dL)	(%)
Hemoglobin	10.0 g/L	1000	466.4	16.9	-4.8
Lipids (Triglycerides)	11.3 mmol/L	1000	463.7	16.8	-4.5
Bilirubin	171 µmol/L	25	469.2	17.0	-1.9
Urea Nitrogen	71.4 mmol/L	200	554.8	20.1	-4.4

Gabriel J. Muraca, Jr.

5/21/99
Date

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Manager Regulatory Affairs
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SUMMARY OF SAFETY AND EFFECTIVENESS

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

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

INTENDED USE

This in vitro method is intended to quantitatively measure iron (Fe) in human serum and plasma on the Bayer ADVIA IMS. Measurements of iron are used in the diagnosis, monitoring and treatment of a variety of diseases including iron deficiency anemias, hemochromatosis, hemosiderosis from excessive iron intake, and hemolytic anemias.

METHOD		**ADVIA IMS**	**CHEM 1**
Part No.	**Reagents**	B41-3735-43	T01-3328-53
	Calibrators	T03-1291-62	T03-1291-62
Analytical Range		0 to 800 ug/dL	0 to 1200 ug/dL
Precision (Total)		2.8% @ 50.7 ug/dL 1.1% @ 230.1 ug/dL 0.7% @ 438.3 ug/dL	1.9% @ 96 ug/dL 1.3% @ 211 ug/dL 1.2% @ 383 ug/dL
Correlation		Y=0.93X+10.8 ug/dL Where Y=ADVIA IMS X=CHEM 1 N=65 r=0.998 Sy.x=9.75 ug/dL	
Plasma/Serum Equivalence		Y=0.98X+0.46 ug/dL Where Y= plasma X= Serum N = 56 r = 0.99 Sy.x = 3.12 ug/dL	

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Interfering Substances

Bilirubin (unconjugated) 25 mg/dL	7.0%	effect change @ 215 ug/dL Fe
Bilirubin (conjugated) 25 mg/dL	-1.0%	effect change @ 221 ug/dL Fe
Hemoglobin (hemolysate) 500 mg/dL	44.0%	effect change @ 217 ug/dL Fe
Lipemia (Triglycerides) 500 mg/dL	-20.0%	effect change @ 207 ug/dL Fe

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5/21/99

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SUMMARY OF SAFETY AND EFFECTIVENESS

T4 Method for the Bayer ADVIA® IMS Systems

Listed below is a comparison of the performance between the Bayer ADVIA IMS T4 method and a similar device that was granted clearance of substantial equivalence (Technicon Immuno 1® method). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA IMS T4 method sheet and the Immuno 1 method sheet.

INTENDED USE

This in vitro method is intended to quantitatively measure T4 in human serum and plasma on the Bayer ADVIA IMS systems. Measurements of T4 are used to aid in the diagnosis and treatment of thyroid diseases.

METHOD		**ADVIA IMS**	**Immuno 1**
Part No.	**Reagents**	B41-3855-42 B41-3855-43	T01-3260-51
	Calibrators	B46-4092-01	T03-3174-01
Minimum Det. Conc.		0.25 µg/dL	0.4 µg/dL
Precision (Total)			
		6.0% @ 3.5µg/dL 5.1% @ 7.9 µg/dL 4.7% @14.9 µg/dL	3.6% @ 4.7 µg/dL 2.6% @ 8.2 µg/dL 2.5% @ 15.7 µg/dL
Correlation	SERUM	y = 1.06 x +0.11 where y = ADVIA IMS x = Immuno 1 n = 72 r = 0.994 Syx = 0.65 µg/dL	
	PLASMA	y = 0.98X + 0.06 Where y = Serum (ADVIA IMS) x = Plasma (ADVIA IMS) n = 24 r = 0.977 Syx = 0.36	

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5/31/99

Interference Substance	Interfering Substance Concentration	Thyroxine Concentration, ug/dL	Effect % Change
Bilirubin (unconjugated)	25 mg/dL	15.3	0
Bilirubin (conjugated)	20 mg/dL	15.2	-2
Hemoglobin	600 mg/dL	15.2	-3
Lipemia (Triglycerides)	1000 mg/dL	15.0	+3

5/21/99

SUMMARY OF SAFETY AND EFFECTIVENESS

Free T4 Assay for Bayer ADVIA® Integrated Modular System

Listed below is a comparison of the performance between the ADVIA FREE T4 (Free Thyroxine) method, and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1® FREE T4 Assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA FREE T4 insert and the Immuno 1® FREE T4 Assay method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure the unbound FREE T4 in human serum by using the ADVIA FREE T4 Assay on the *Bayer ADVIA®* Integrated Modular System. Less than 0.05% of the Total T4 is unbound to the serum proteins and it is this Free T4 fraction that directly regulates metabolic activity. Thus Free T4 measurements are generally used in the direct or first line diagnosis of thyroid disorders.

METHOD	**ADVIA FREE T4 Assay**		**Immuno 1 FREE T4 Assay** (predicate Device)	
Part No.	Reagents Reagents Calibrators	B42-3905-41 (100 tests) B42-3905-42 (250 tests) B43-3936-01	Reagents Calibrators	T01-3360-51 T03-3401-01
Minimum Detectable Conc.	0.05 ng/dL		0.10 ng/dL	
Precision (Total CV)	4.5% @ 0.85 ng/dL 4.8% @ 1.46 ng/dL 3.0% @ 3.04 ng/dL		4.9% @ 0.94 ng/dL 3.5% @ 1.76 ng/dL 2.2% @ 4.68 ng/dL	

Correlation

$y = 0.998\ x + 0.2179$

where

y = ADVIA FREE T4 Assay
x = Immuno 1 FREE T4 Assay
n = 50
r = 0.9928
S_{yx} = 0.1368 ng/dL

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, µIU/mL		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	10 g/L	1000	1.83	1.76	3.8
Lipids (Triglycerides)	11.3 mmol/L	1000	1.84	1.88	2.2
Bilirubin	428 µmol/L	25	1.78	1.79	0.6
Urea Nitrogen	71.4 mmol/L	200	1.83	1.81	1.1

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SUMMARY OF SAFETY AND EFFECTIVENESS

Total T3 Assay for Bayer ADVIA® Integrated Modular System

Listed below is a comparison of the performance between the ADVIA T3 (Triiodothyronine) method, and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1® T3 Assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA T3 insert and the Immuno 1® T3 Assay method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure T3 in human serum using ADVIA T3 Assay on a *Bayer ADVIA®* Integrated Modular System. Measurements of T3 are used in the diagnosis and treatment of thyroid disorders such as hyperthyroidism.

METHOD	**ADVIA T3 Assay**		**Immuno 1 T3 Assay** (predicate Device)	
Part No.	Reagents	B42-3916-41 (100 tests)	Reagents	T01-2942-01
	Reagents	B42-3916-42 (250 tests)	Calibrators	T03-2872-01
	Calibrators	B43-3943-01		
Minimum Detectable Conc.	0.13 ng/mL		0.06 ng/mL	
Precision (Total CV)	10.3%@ 0.67 ng/mL		13.3% @ 0.46 ng/mL	
	4.9% @ 1.74 ng/mL		6.0% @ 1.34 ng/mL	
	3.6% @ 2.89 ng/mL		3.9% @ 3.43 ng/mL	

Correlation $y = 1.014x + 0.1368$

where
y = ADVIA T3 Assay
x = Immuno 1 T3 Assay
n = 50
r = 0.996
S_{yx} = 0.10 ng/mL

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, ng/mL		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	10 g/L	1000	1.85	1.91	3.7
Lipids (Triglycerides)	11.3 mmol/L	1000	1.85	1.95	5.5
Bilirubin	428 µmol/L	25	1.85	1.90	3.0
Urea Nitrogen	71.4 mmol/L	200	1.85	1.95	5.6

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5/21/99

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SUMMARY OF SAFETY AND EFFECTIVENESS

Free T3 Assay for Bayer ADVIA® Integrated Modular System

Listed below is a comparison of the performance between the ADVIA Free T3 Assay method and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1® Free T3 Assay). The information used in the Summary of Safety and Effectiveness was extracted from the ADVIA Free T3 insert and the Immuno 1® Free T3 Assay method sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure Free T3, in human serum using ADVIA Free T3 Assay on a *Bayer ADVIA®* Integrated Modular System. Measurements of Free T3 are used in the diagnosis of thyroid or pituitary disorders.

METHOD	**ADVIA Free T3 Assay**	**Immuno 1 Free T3 Assay** (predicate Device)
Part No.	Reagents B42-3904-42 Calibrators B43-3935-01	Reagents T01-3662-51 Calibrators T03-3663-01
Minimum Detectable Conc.	0.4 pg/mL	0.3 pg/mL
Precision (Total CV)	10.0% @ 2.0 pg/mL 5.0% @ 4.88 pg/mL 4.1% @ 9.35 pg/mL	8.5% @ 1.8 pg/mL 3.8% @ 5.4 pg/mL 2.9% @ 10.8 pg/mL
Correlation	$y = 0.97x + 0.41$ where y = ADVIA Free T3 Assay x = Immuno 1 Free T3 Assay n = 56 r = 0.998 S_{yx} = 0.427 pg/mL	

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, pg/mL		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	10 g/L	1000	4.66	5.35	6.4
Lipids (Triglycerides)	11.3 mmol/L	1000	4.80	5.30	9.4
Bilirubin	428 µmol/L	25	4.66	4.50	-3.4
Urea Nitrogen	153.1mmol/L	429	4.66	4.76	2.1

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Date

SUMMARY OF SAFETY AND EFFECTIVENESS

T-Uptake Assay for Bayer ADVIA® Integrated Modular System

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

INTENDED USED

This *in vitro* method is intended to quantitatively measure the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroxine-binding globulin, thyroxine-binding prealbumin, and albumin in human serum using the ADVIA T-Uptake Assay on the *Bayer ADVIA®* Integrated Modular System. Measurements of T-Uptake are used in the diagnosis and treatment of thyroid disorders.

METHOD	**ADVIA T-Uptake Assay**		**Immuno 1 T-Uptake Assay** (predicate Device)	
Part No.	Reagents Calibrators	B42-3915-41 (100 tests) B43-3994-01	Reagents Calibrators	T01-3036-51 T03-3076-01
Minimum Detectable Conc.	N/A		N/A	
Precision (Total CV)	3.2% @ 0.96 2.6% @ 0.89 2.3% @ 1.14		2.8% @ 0.71 2.6% @ 1.03 2.4% @ 1.41	
Correlation	$y = 0.96x + 0.0003$ where y = ADVIA T-UptakeAssay x = Immuno 1 T-Uptake Assay n = 51 r = 0.987 S_{yx} = 0.03			

Interfering Substances

Interfering Substance	Interfering Substance Concentration		Analyte Concentration, ratio		Effect
	SI Units	(mg/dL)	Expected	Observed	(%)
Hemoglobin	10 g/L	1000	1.13	1.14	0.88
Lipids (Triglycerides)	11.3 mmol/L	1000	1.11	1.11	0.90
Bilirubin	428 µmol/L	25	1.15	1.17	1.74
Urea Nitrogen	71.4 mmol/L	200	1.10	1.11	0.91

Gabriel J. Muraca, Jr. — Date: 5/21/99

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Urea Nitrogen method for ADVIA® 400

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 urea nitrogen (an end product of nitrogen metabolism) in human serum, plasma or urine on the Bayer ADVIA 400 system

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Technicon CHEM 1® Urea Nitrogen	T01-1452-53	T03-1291-62

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA 400 Urea Nitrogen	B41-3745-26	T03-1291-62

A. Imprecision(SERUM)

ADVIA 400	
Level (mg/dL)	Total CV(%)
7.3	4.3
17	2.5
52	1.6

CHEM 1	
Level (mg/dL)	Total CV(%)
21	3.6
54	3.7
97	3.4

B. Imprecision(URINE)

ADVIA 400	
Level (mg/dL)	Total CV(%)
69	3.9
212	2.1
404	2.0

CHEM 1	
Level (mg/dL)	Total CV(%)
478	2.6
648	2.5

Correlation (Y=ADVIA 400, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	CHEM 1	50	Y=1.03X-0.6	2.8	0.997	5-124
Plasma(y), Serum(x)	ADVIA 400	58	Y=0.96X+0.6	1.1	0.975	6-32
Urine	CHEM 1	53	Y=1.08X-8.9	22.5	0.997	70-1010

Gabriel J. Manaca Jr. 5/21/99
Manager RA

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Urea Nitrogen Conc. (mg/dL)	Effect (% change)
Bilirubin	33	17.6	-4.0
Hemoglobin	500	36.1	+4.4
Lipids (Triglycerides)	500	30.5	+23.0
Ascorbic Acid	400	58.5	+3.2
Salicylate	500	66.3	-2.4
Glucose	500	61.9	+9.5
Acetominophen	40	52.9	+4.5

Analytical Range

Serum/Plasma: 0 to 150 mg/dL
Urine: 2 to 1030 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1999

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

Re: K991817
Trade Name: Additional IMS Assays for the Bayer ADVIA® IMS™ System
Regulatory Class: II
Product Code: CIJ
Dated: May 21, 1999
Received: May 27, 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): K991817

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

Indications For Use:

The *Bayer ADVIA IMS* Amylase assay is an *in vitro* diagnostic device intended to measure amylase activity in human serum, plasma or urine. Such measurements are used as an aid primarily in the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

The *Bayer ADVIA IMS* Cortisol assay is an *in vitro* diagnostic device intended to quantitatively measure cortisol in human serum. Measurements of cortisol are used as an aid in the diagnosis and treatment of disorders of the adrenal gland.

The *Bayer ADVIA IMS* Iron assay is an *in vitro* diagnostic device intended to measure iron in human serum or plasma. Measurements of iron are used as an aid in the diagnosis, monitoring and treatment of a variety of diseases including iron deficiency anemias, hemochromatosis, hemosiderosis from excessive iron intake, and hemolytic anemias.

(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)

510(k) Number (if known):

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

Indications For Use:

The *Bayer ADVIA IMS* Thyroxine assay is an *in vitro* diagnostic device intended to measure thyroxine (T4), both protein bound and free, in human serum and plasma. Measurements of T4 are used as an aid in the diagnosis and treatment of thyroid diseases.

The *Bayer ADVIA IMS* Free Thyroxine (FT4) assay is an *in vitro* diagnostic device intended to quantitatively measure free thyroxine in human serum. Measurements of free thyroxine in conjunction with other thyroid tests and clinical indicators are used as an aid in the diagnostic discrimination and assessment of thyroid diseases.

The *Bayer ADVIA IMS* Triiodothyronine (T3) assay is an *in vitro* diagnostic device intended to quantitatively measure triiodothyronine (T3) in human serum. Measurements of triiodothyronine, in conjunction with other thyroid tests and clinical indicators, are used as an aid in the diagnostic discrimination and assessment of thyroid diseases.

(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)

510(k) Number (if known):

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

Indications For Use:

The *Bayer ADVIA IMS* Free Triiodothyronine (FT3) assay is an *in vitro* diagnostic device intended to quantitatively measure free triiodothyronine in human serum. Measurements of free triiodothyronine, in conjunction with other first-line thyroid tests such as Thyroid Stimulating Hormone (TSH) and Free Thyroxine (Free T4), as well as other clinical indicators, are used as an aid in the diagnostic discrimination and assessment of thyroid diseases.

The *Bayer ADVIA IMS* T Uptake (TUP) assay is an *in vitro* diagnostic device intended to quantitatively measure the total amount of available binding sites for thyroid hormone on the thyroxine-binding proteins, globulin, pre-albumin, and albumin in human serum. Measurements of T Uptake, in conjunction with other thyroid tests and clinical indicators, are used as an aid in the diagnostic discrimination and assessment of thyroid diseases.

The *Bayer ADVIA IMS* Urea Nitrogen (BUN) method is an *in vitro* diagnostic device intended to measure urea nitrogen in human serum, plasma and urine. Such measurements are used as an aid in the diagnosis and treatment of certain renal and metabolic diseases.

Han Coop

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991817

(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)