

DEC 16 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
β2-Microglobulin Assay for Bayer ADVIA® Integrated Modular System (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: K993711

1. Intended Use

The Bayer ADVIA® IMS β2-Microglobulin (β2M) assay is an *in vitro* diagnostic device intended to quantitatively measure β2-Microglobulin in human serum and urine. When used in conjunction with clinical data and other diagnostic procedures, measurements of β2-Microglobulin aid in the management of patients with renal dysfunction and rheumatoid arthritis.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 β2-Microglobulin Assay	T01-3669-51	T03-3670-01

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS β2-Microglobulin Assay	B42-3892-21	B43-3924-01

Imprecision

ADVIA IMS	
Level (mg/L)	Total CV(%)
1.03	2.5
4.01	3.2

Immuno 1	
Level (mg/L)	Total CV(%)
1.3	5.1
2.3	3.1

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/L)	R	Sample Range (mg/L)
Serum	Immuno 1	86	Y=1.009X+0.055	0.442	0.996	0.72-18.9
Urine	Immuno 1	50	Y=0.923X+0.004	0.012	0.990	0.03-0.372

Interfering Substances

Interfering Substance	Interfering Substance Concentration mg/dL	Analyte Concentration (mg/L)	Effect (% change)
Hemoglobin	1000	0.86	-6.18
Lipids (Triglycerides)	1000	0.37	4.68
Bilirubin	25	0.44	4.92
Creatinine	2.5	0.74	-3.68
Urea	200	0.73	4.35
Albumin	6500	1.36	8.90
Immunoglobulin	6000	0.39	4.56

Gabriel J. Murray Jr.
 10/21/99 - RA

Analytical Range

Serum: 0.001 – 20 mg/L

Urine: 0.001 – 10 mg/L

Minimum Detectable Concentration

ADVIA IMS (mg/L)	Immuno 1 (mg/L)
0.001	0.01



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10/21/99

Date

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CK-MB 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: K993711

1. Intended Use

This *in vitro* diagnostic method is intended to measure CK-MB in human serum or plasma on the Bayer ADVIA IMS system

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 CK-MB I	T01-3587-51	T03-3586-01

3. Device / Method

Product Name	Reagent Part #	BAN	Calibrator Part #	BAN
ADVIA IMS CK-MB I	B42-3898-22	05509473	B43-3930-01	02852592

Minumum Detectable Conc.

Method	ADVIA	Immuno 1
MDC	0.05 ng/mL	0.1 ng/mL

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
2.3	5.9
11.6	4.1
42.4	4.1

Immuno 1	
Level (ng/mL)	Total CV(%)
4.6	6.1
8.1	5.1
73.9	5.1

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

Specimen type	Comparison System (X)	N	Regression Equation	Sy.X (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	75	Y=0.98 - 0.09	0.79	0.999	0.1 - 79.9
Plasma	Immuno 1	50	Y=0.98 - 0.25	1.33	1.0	0.2 - 73.0

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Myoglobin Conc (ng/mL)	Effect (% change)
Bilirubin	25	41.1	1.9
Hemoglobin	1000	39.9	5.8
Urea Nitrogen	200	39.9	10.0
Lipids (Triglycerides)	1000	44.0	0.0

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Analytical Range

Serum/Plasma: 0.05 to 300 ng/mL



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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Myoglobin 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: K993711

1. Intended Use

This *in vitro* diagnostic method is intended to measure Myoglobin in human serum or plasma on the Bayer ADVIA IMS system

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 Myoglobin	T01-3653-51	T03-3654-01

3. Device / Method

Product Name	Reagent Part #	BAN	Calibrator Part #	BAN
ADVIA IMS Myoglobin	B42-3909-21	03514070	B43-3938-01	06268712

Minimum Detectable Conc.

Method	ADVIA	Immuno 1
MDC	0.22 ng/mL	1.3 ng/mL

Imprecision

ADVIA IMS		Immuno 1	
Level (ng/mL)	Total CV(%)	Level (ng/mL)	Total CV(%)
12.7	1.6	14.4	3.0
64.5	2.6	73.5	3.7
577.6	3.1	630.1	2.8

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

Specimen type	Comparison System (X)	N	Regression Equation	Sample Range (ng/mL)
Serum	Immuno 1	49	Y=1.02X-0.80	11 - 5885
Plasma	Immuno 1	61	Y=1.10X-4.54	35 - 2362

Passing-Bablok correlation used

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Myoglobin Conc (ng/mL)	Effect (% change)
Bilirubin	25	534.6	6.6
Hemoglobin	1000	577.6	-1.6
Creatinine	2.5	540.7	5.7
Urea Nitrogen	200	536.8	7.0
Lipids (Triglycerides)	1000	452.8	1.5

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Analytical Range

Serum/Plasma: 0.22 to 3000 ng/mL



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Date

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Testosterone Assay for Bayer ADVIA® Integrated Modular System (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: K993711

1. Intended Use

This *in vitro* method is intended to quantitatively measure Testosterone, in human serum using ADVIA IMS Testosterone Assay on a Bayer ADVIA® Integrated Modular System. The measurement of serum testosterone in men is useful in the assessment of infertility, impotence and sexual development in young adults. The clinical symptoms of excess testosterone in female including hirsutism, virilization, amenorrhea, infertility and obesity.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 Testosterone Assay	T01-3694-51	T03-3695-01

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS Testosterone Assay	B42-3917-21	B43-3945-01

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
0.9	7.1
2.7	4.2
7.7	3.4

Immuno 1	
Level (ng/mL)	Total CV(%)
0.95	7.8
3.04	4.8
8.43	3.0

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	77	Y=0.91X+0.073	0.328	0.993	0.04-12.2

Interfering Substances

Interfering Substance	Interfering Substance Concentration mg/dL	Analyte Concentration (ng/mL)	Effect (% change)
Human IgG	6000	2.2	6.7
Hemoglobin	1000	3.1	-8.2
Lipids (Triglycerides)	1000	2.2	-1.8
Bilirubin	25	2.2	-3.9
Urea	429	2.3	-1.3

Gabriel J. Monaca Jr
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Analytical Range
0.05 – 20 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.05	0.05



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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Troponin I 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: K993711

1. Intended Use

This *in vitro* diagnostic method is intended to measure Troponin I in human serum or plasma on the Bayer ADVIA IMS system

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno I Troponin I	T01-3887-51	T03-3888-01

3. Device / Method

Product Name	Reagent Part #	BAN	Calibrator Part #	BAN
ADVIA IMS Troponin I	B42-3920-22	06120626	B43-3947-01	06956201

Minimum Detectable Conc.

Method	ADVIA	Immuno I
MDC	0.1 ng/mL	0.1 ng/mL

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
1.9	3.6
7.2	2.0
51.9	1.8

Immuno I	
Level (ng/mL)	Total CV(%)
2.9	3.3
6.9	2.3
47.4	2.0

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 I	59	Y=0.96 + 0.26	0.47	0.999	0.1 - 70
Plasma	Immuno I	52	Y=0.99 + 0.22	0.34	0.999	0.1 - 50

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Troponin I Conc (ng/mL)	Effect (% change)
Bilirubin	25	6.08	-0.3
Hemoglobin	1000	7.14	-4.5
Urea Nitrogen	200	6.2	-1.6
Lipids (Triglycerides)	1000	6.15	0.5

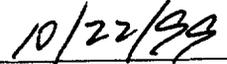
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Analytical Range

Serum/Plasma: 0.1 to 200 ng/mL



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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Ferritin 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: K993711

1. Intended Use

This *in vitro* diagnostic method is intended to measure Ferritin in human serum on the Bayer ADVIA IMS system.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 Ferritin	T01-2863-51	T03-4311-01

3. Device / Method

Product Name	Reagent Part #	BAN	Calibrator Part #	BAN
ADVIA IMS Ferritin	B42-3902-22	05782072	B43-3933-01	02467486

Minimum Detectable Conc.

Method	ADVIA	Immuno 1
MDC	0.1 ng/mL	0.3 ng/mL

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
51.4	3.0
124	3.2
506	3.0

Immuno 1	
Level (ng/mL)	Total CV(%)
21.1	7.0
148.1	5.0
344.1	5.0

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

Specimen type	Comparison System (X)	N	Regression Equation	Sample Range (ng/mL)
Serum	Immuno 1	50	Y=1.01X-5.86	1.7 - 1656

Passing-Bablok Correlation used

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Ferritin Conc (ng/mL)	Effect (% change)
Bilirubin	30.5	156.1	-1.7
Hemoglobin	1000	169.9	-2.0
Urea Nitrogen	200	152.6	2.0
Lipids (Triglycerides)	1000	146.8	-7.4

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Analytical Range

Serum/Plasma: 0.1 to 2500 ng/mL



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Date

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
hCG Assay for Bayer ADVIA® Integrated Modular System (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: K993711

1. Intended Use

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

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 hCG Assay	T01-2966-51	T03-3148-01

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS hCG Assay	B42-3907-43	B43-3941-01

Imprecision

ADVIA IMS	
Level (mIU/mL)	Total CV(%)
12.1	4.2
23.9	4.5
198.1	5.5

Immuno 1	
Level (mIU/mL)	Total CV(%)
18.3	4.0
55.7	3.7
198.1	3.7

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mIU/mL)	R	Sample Range (mIU/mL)
Serum	Immuno 1	40	Y=0.990X+1.96	17.5	1.0	0.1 - 1345
Plasma(y), Serum(x)	ADVIA IMS	51	Y=0.956X+0.868	17.0	0.998	0.1 - 902
Urine	Immuno 1	87	Y=1.016X-2.467	12.3	1.0	0.1-1158

Interfering Substances (Serum)

Interfering Substance	Interfering Substance Concentration mg/dL	hCG Concentration (mIU/mL)	Effect (% change)
Hemoglobin	1000	17.2	-2.3
Lipids (Triglycerides)	1000	17.2	-8.7
Bilirubin	25	16.5	-6.1
Urea Nitrogen	200	17.2	-7.6

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11/26/99

Interfering Substances (Urine)

Interfering Substance	Interfering Substance Concentration mg/dL	hCG Concentration (mIU/mL)	Effect (% change)
Hemoglobin	10	16.7	7.2
Creatinine	500	17.1	0.0
Bilirubin	200	18.2	0.0
Urea Nitrogen	1000	18.5	0.0
Uric Acid	150	18.8	- 4.3
Vitamin C	500	16.9	5.9

Analytical Range

0.1 - 1000 mIU/mL

Minimum Detectable Concentration

ADVIA IMS (mIU/mL)	Immuno 1 (mIU/mL)
0.1	0.5



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10/26/99
Date

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
3rd Generation TSH Assay for Bayer ADVIA[®] Integrated Modular System (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: 6993711

1. Intended Use

This *in vitro* method is intended to quantitatively measure TSH, Thyroid Stimulating Hormone, in human serum and plasma (lithium heparin) using ADVIA IMS 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 μ IU/mL, as defined by the American Thyroid Association.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 TSH Assay	T01-2942-51	T03-3568-01

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS TSH Assay	B42-3921-43	B43-3948-01

Imprecision

ADVIA IMS		Immuno 1	
Level (μ IU/mL)	Total CV(%)	Level (μ IU/mL)	Total CV(%)
0.02	13.2		
0.52	2.9	1.3	6.3
4.95	2.3	9.0	2.0
31.1	2.6	22.5	1.8

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (μ IU/mL)	R	Sample Range (μ IU/mL)
Serum	Immuno 1	50	Y=0.98X-0.357	1.48	0.997	0.06 - 76.0
Plasma(y), Serum(x)	ADVIA IMS	46	Y=1.01X-0.044	0.21	1.0	0.12 - 63.3

Interfering Substances

Interfering Substance	Interfering Substance Concentration mg/dL	TSH Concentration (μ IU/mL)	Effect (% change)
Hemoglobin	1000	3.32	1.8
Lipids (Triglycerides)	1000	3.49	-1.15
Bilirubin	25	3.25	1.5
Urea Nitrogen	1000	3.30	0.3

Gabriel J. Minahan, Jr
10/26/99

Analytical Range
0.005– 100 μ IU/mL

Minimum Detectable Concentration

ADVIA IMS (μ IU/mL)	Immuno 1 (μ IU/mL)
0.005	0.03



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Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 16 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
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Re: K993711
Trade Name: Additional IMS Assays for the Bayer Advia IMS™ System
Regulatory Class: II
Product Code: JZG, JHW, DDR, JLW, JMG, DHA
Regulatory Class: I
Product Code: CDZ, MMI
Dated: October 27, 1999
Received: November 3, 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 (Pre-market 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.

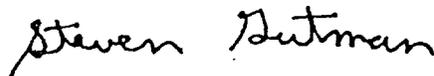
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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): K993711

Device Name: **β2-Microglobulin (B2M)**

Indications For Use:

The Bayer Advia IMS β2-Microglobulin (B2M) assay is an *in vitro* diagnostic device intended to quantitatively measure β2-Microglobulin in human serum and urine. When used in conjunction with clinical data and other diagnostic procedures, measurements of β2-Microglobulin aid in the management of patients with renal dysfunction and rheumatoid arthritis.

Device Name: **Creatine Kinase – MB Isoenzyme (CKMB)**

Indications For Use:

The Bayer Advia IMS Creatine Kinase (CKMB) assay is an *in vitro* diagnostic device intended to quantitatively measure the MB isoenzyme in human serum and plasma. When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurements of CK-MB aid in the diagnosis of acute myocardial infarction (AMI).

Device Name: **Myoglobin (MYO)**

Jean Cooper
(Division Sign)
Division
510(k) *K993711*

Indications For Use:

The Bayer Advia IMS Myoglobin assay is an *in vitro* diagnostic device intended to quantitatively measure the myoglobin in human serum and plasma. When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurements of myoglobin aid in the diagnosis of acute myocardial infarction (AMI).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Formal 1-2-96

510(k) Number (if known): K993711

Device Name: **Testosterone**

Indications For Use:

The Bayer Advia IMS Testosterone assay is an *in vitro* diagnostic device intended to quantitatively measure total testosterone in human serum. Measurements of testosterone are used in the diagnosis and treatment of various hormonal sexual disorders. This diagnostic method is not intended for use on any other diagnostic system.

Device Name: **Troponin I (TNI)**

Indications For Use:

The Bayer Advia IMS Troponin I assay is an *in vitro* diagnostic device intended to quantitatively measure the cardiac Troponin I in human serum and plasma. When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurements of cardiac Troponin I aid in the diagnosis of acute myocardial infarction (AMI).

Device Name: **Ferritin (FERR)**

Indications For 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.

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Division Sign-Off)
Division of Clinical Laboratory Devices
Number K993711

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Formal 1-2-96

510(k) Number (if known): K993711

Device Name: **Human Chorionic Gonadotropin (hCG)**

Indications For Use:

The Bayer Advia IMS hCG assay is an *in vitro* diagnostic device intended to quantitatively measure total beta (β) human chorionic gonadotropin (hCG) in human serum, plasma, and urine. Measurements of human chorionic gonadotropin are used in the detection of pregnancy.

Device Name: **Thyroid Stimulating Hormone (TSH)**

Indications For Use:

The Bayer Advia IMS TSH assay is an *in vitro* diagnostic device intended to quantitatively measure thyroid stimulating hormone (TSH) in human serum, plasma. 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 mIU/L or μIU/mL, as defined by the American Thyroid Association. Measurements of thyroid stimulating hormone are used in the diagnosis of thyroid or pituitary disorders.

Jean Cooper
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of Clinical Laboratory Devices
Number K993711

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Formal 1-2-96