OCT 01 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
AFP 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: K020807

1. Intended Use

The *Bayer ADVIA® IMS™* AFP assay is an *in vitro* diagnostic device intended to quantitatively measure α-fetoprotein (AFP) in human serum on the *Bayer* ADVIA IMS system as an aid in the management of nonseminomatous testicular cancer. AFP values obtained using the *Bayer* ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined. ***AFP testing is not recommended as a screening procedure to detect cancer in the general population.***

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 AFP Assay	T01-3100-51	T03-3187-01

3. Device / Method

Product Name	Reagent Part # / BAN Number	Calibrator Part # / BAN Number
ADVIA IMS AFP Assay	B42-3890-23 / 09750523 (100 tests) 01440029 (250 tests)	B43-3923-01 / 09022137

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
4.6	2.3
18.97	2.7
93.52	2.6

Immuno 1	
Level (ng/mL)	Total CV(%)
20	2.1
50	2.2
200	3.6

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

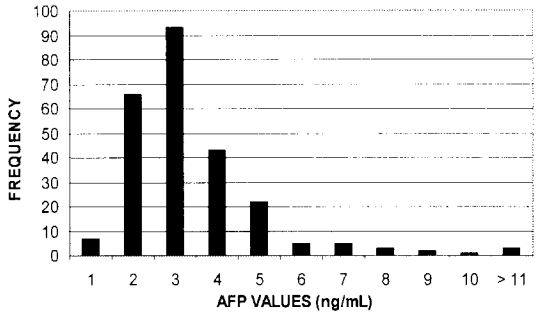
Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	50	Y=1.06 * X -3.18	5.82	0.998	0.71 – 338.92

Interfering Substances

Interfering Substance	Interfering Substance Concentration mg/dL	AFP Concentration (ng/mL)	Effect (% change)
Hemoglobin	1000	10.2	5.6
Lipids (Triglycerides)	1000	19.8	7.5
Bilirubin	25	21.3	-4.5
IgG	6.0	16.4	8.3
Albumin	6.5	14.8	4.8

Expected values[1]

As with all tests, each laboratory should establish its own reference range. In a group of 250 healthy people, 97.5% of the serum AFP values were found to be 0.8 ng/mL (0.66 IU/mL) to 8.9 ng/mL (7.35 IU/mL). The distribution of the AFP values for these 250 patient samples is shown in Figure 1. Substantially higher values are often found when malignant disease is present, particularly in patients with nonseminomatous tumors. However, low AFP values do not rule out the presence of malignant disease.



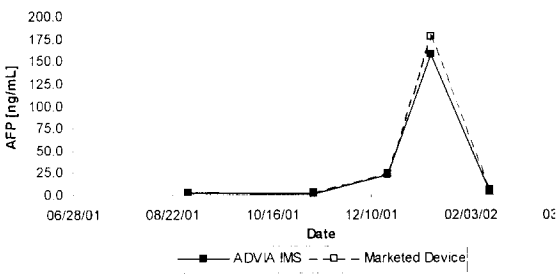
DISTRIBUTION OF SERUM AFP ASSAY VALUES

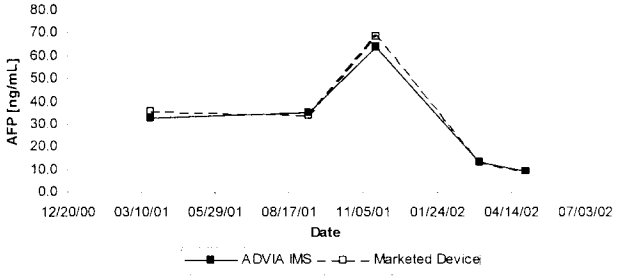
PATIENT POPULATION	N	AFP ASSAY VALUES (ng/mL)				MEDIAN
		0 – 8.9 (%)	>8.9 – 100 (%)	>100 – 400 (%)	>400 (%)	
Healthy Subjects	350	98.3	1.7	0.0	0.0	2.5
Testicular Cancer nonseminomatous	100	36.0	40.0	14.0	10.0	20.2
Testicular Cancer mixed germ cell tumor	46	43.5	45.7	6.5	4.3	11.6
Testicular Cancer seminomatous	8	75.0	25.0	0.0	0.0	2.5
Prostate Cancer / Bladder Cancer	40	97.5	2.5	0.0	0.0	3.4
Lung Cancer	29	96.6	0.0	0.0	3.4	3.8
Colorectal Cancer	38	89.5	10.5	0.0	0.0	4.5
Liver Cancer	67	0.0	31.3	20.9	47.8	310.9
Breast Cancer	10	80.0	20.0	0.0	0.0	4.8
Cirrhosis	50	88.0	12.0	0.0	0.0	4.0
Hepatatis	50	88.0	12.0	0.0	0.0	3.9
Benign Genito-urinary disease	29	93.1	0.06.9	0.0	0.0	3.1
Other nonmalignant	37	100.0	0.0	0.0	0.0	2.3

[1] Immuno 1 data on file

Monitoring data

Two examples of serial patient monitoring studies using Bayer ADVIA IMS assay results in comparison to results obtained for another marketed device are shown in the following figures.





Analytical Range

0.08 – 400 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.08	0.1

4. Conclusion

Performance of the ADVIA IMS AFP Assay on a *Bayer ADVIA*® IMS™ is equivalent to the performance of the AFP Assay on the predicate device (Immuno 1) and is within proposed specifications. No safety and effectiveness issues have been raised

Kenneth T. Edds
Director Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth T. Edds, Ph.D.
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

OCT 01 2002

Re: k020807
Trade/Device Name: AFP (α-Fetoprotein) Assay for the ADVIA® IMS™
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LOJ
Dated: August 29, 2002
Received: September 3, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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: K020807

Device Name: AFP (α-Fetoprotein) Assay for the ADVIA® IMS™

Indications for Use:

The *Bayer ADVIA® IMS™* AFP assay is an *in vitro* diagnostic device intended to quantitatively measure α-fetoprotein (AFP) in human serum on the *Bayer* ADVIA IMS system as an aid in the management of nonseminomatous testicular cancer. AFP values obtained using the *Bayer* ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined. ***AFP testing is not recommended as a screening procedure to detect cancer in the general population.***

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Deborah M. Moore

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020807

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)