

NOV 12 2002

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CA 15-3 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: K022178 (leave blank)

1. Intended Use

This *in vitro* immunoassay is intended to quantitatively measure CA 15-3 values in human serum. When used in conjunction with other clinical and diagnostics procedures, serial testing using ADVIA IMS CA 15-3 Assay on a Bayer ADVIA[®] IMS[™], is indicated for monitoring the course of disease and therapy in metastatic breast cancer patients, and for the detection of recurrence in previously treated Stage II, with greater than two positive lymph nodes, or Stage III breast cancer patients.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 CA 15-3	T01-3553-51	T03-3554-01

3. Device / Method

Product Name	Reagent Part # / BAN #	Calibrator Part # / BAN #
ADVIA IMS CA 15-3 Assay	B42-3894-41 / 08623765	B43-3926-01 / 05523158

A. Imprecision

ADVIA IMS	
Level (U/mL)	Total CV (%)
12.3	4.7
29.6	5.5
59.1	5.3

Immuno 1	
Level (U/mL)	Total CV(%)
13.5	4.0
33.2	3.3
102.3	3.4

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (U/mL)	R	Sample Range (U/mL)
Serum	Immuno 1	73	1.061 * X+ 1.50	3.04	0.996	7.02-184.9

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	CA 15-3 Conc. (U/mL)	Effect (% change)
Hemoglobin	1000	16.2	1.1
Lipids (Triglycerides)	1000	27.4	2.5
Bilirubin	25	35.5	0.1
IgG	6000	31.5	2.3
Albumin	6000	28.0	4.6

Analytical Range : 0.04 – 200 U/mL

Minimum Detectable Concentration

ADVIA IMS (U/mL)	Immuno 1 (U/mL)
0.04	0.2

4. Conclusion

Performance of the ADVIA IMS CA 15-3 Assay on a a *Bayer ADVIA*[®] IMS[™] is equivalent to the performance of the CA 15-3 Assay on the predicate device (Immuno 1) and is within proposed specifications. No safety and effectiveness issues have been raised.



Kenneth T. Edds
 Manager Regulatory Affairs
 Bayer Corporation
 511 Benedict Avenue, Tarrytown, NY 10591.

7/01/02
 Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 2002

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

Re: k022178
Trade/Device Name: CA15-3 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: MOI, JIT
Dated: October 25, 2002
Received: October 29, 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.

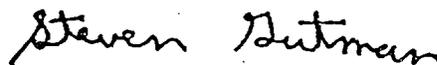
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 -

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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: K022178

Device Name: CA15-3 Assay for the ADVIA® IMS™

Indications for Use:

The Bayer ADVIA® IMS™ CA 15-3 Assay is an *in vitro* diagnostic device intended to quantitatively measure CA 15-3 Assay values in human serum. When used in conjunction with other clinical and diagnostic procedures, serial testing with CA 15-3 Assay results are useful in monitoring the course of disease and therapy in metastatic breast cancer patients, and for the detection of recurrence in previously treated Stage II, with greater than two positive lymph nodes, or Stage III breast cancer patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. P. Reeves

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022178

Prescription Use ✓
CounterUse _____
(Per 21 CFR 801.109)

OR Over-The-