

Premarket Notification – 510(k)

JAN 30 2003

ADVIA Centaur HER-2/neu Immunoassay

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

The assigned 510(k) number is:

7.1 General Information

Date of Summary Update: November 22, 2002

Applicant: Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
Phone: 914-524-2446
Fax: 914-524-2500
Ken.edds.b@bayer.com

Owner: Bayer Corporation
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
Establishment Registration No: 2432235

Manufacturer: Bayer Corporation
333 Coney Street
Walpole, MA 02032
Establishment Registration No: 1219913

Device Name: ADVIA Centaur® HER-2/neu assay

Common or Usual Name: Chemiluminescence immunoassay kit for the
determination of HER-2/neu antigen
using Bayer Corporation's
ADVIA Centaur automated analyzer.

Classification:
Name: Tumor associated antigen immunological system
Class: II
CFR: 866.6010
Product Code: 82 NCW

This submission was prepared in accordance with "Guidance Document for Submission of Tumor Associated Antigen Premarket Notifications".

Substantial Equivalence To: Bayer Immuno-1 HER-2/neu

510(k) Number: K992228

7.2 Intended Use

For *in vitro* diagnostic use in the quantitative determination of the HER-2/*neu* protein in human serum or using the ADVIA Centaur® System. HER-2/*neu* values obtained may be used in the follow-up and monitoring of patients with metastatic breast cancer whose initial serum HER-2/*neu* level is greater than 15 ng/mL. HER-2/*neu* values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer. The clinical utility of the measurement of HER-2/*neu* in serum as a prognostic indicator for early recurrence and in the management of patients on immunotherapy has not been fully established. This test should be used by or under the order of a physician. This assay is not intended for use on any other system.

7.3 Device Description

The ADVIA Centaur HER-2/*neu* assay is a fully automated, two-site sandwich immunoassay using direct, chemiluminescent technology. The Lite Reagent is composed of the monoclonal mouse antibody, TA-1 labeled with acridinium ester. The Fluorescein Conjugate Reagent is composed of the monoclonal mouse antibody, NB-3, labeled with fluorescein. The two monoclonal antibodies are specific for unique epitopes on the extracellular domain of HER-2/*neu*. The Solid Phase is composed of purified monoclonal mouse capture antibody, which is covalently coupled to paramagnetic particles. The sample is incubated with Fluorescein Conjugate Reagent and Lite Reagent simultaneously for 5.5 minutes. After this incubation, the Solid Phase is added and the mixture is incubated for an additional 2.75 minutes. After this final incubation, the immuno-complex formed is washed. The measured chemiluminescence is directly proportional to the quantity of HER-2/*neu* antigen in the sample.

7.4 Comparison to the Predicate Device

The ADVIA Centaur HER-2/*neu* immunoassay kit is similar to the Bayer Immuno-1 HER-2/*neu* kit in the indications for use, format, performance characteristics, and results. The ADVIA Centaur tests differ mainly in their signal system as compared to the Immuno-1 principle. In the ADVIA Centaur method, a chemiluminogenic molecule (acridinium ester) is used to replace the Alkaline Phosphatase signal used in the Immuno-1 assay.

7.5 Equivalence to Predicate Device

For 196 samples in the assay range of 0.2-250 ng/mL, the relationship of the ADVIA Centaur HER-2/*neu* assay to the Bayer Immuno 1™ HER-2/*neu* assay is described by the following equation (calculated Linear Least Sum Squares Regression):

$$\text{ADVIA Centaur HER-2/neu} = 0.97 (\text{Immuno 1}) + 0.56 \text{ ng/mL}$$

The correlation coefficient *r* is 0.99

The data demonstrate substantial equivalence of the ADVIA Centaur HER-2/*neu* assay to the FDA-cleared Bayer Immuno-1 HER-2/*neu* assay as an adjunctive test for use in the management (monitoring) of metastatic breast cancer patients during the course of disease and therapy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 30 2003

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

Re: k024017
Trade/Device Name: Bayer ADVIA Centaur HER-2/ neu assay
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: NCW
Dated: November 26, 2002
Received: December 4, 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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

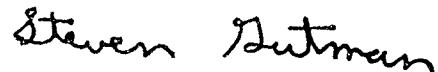
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K024017

Device Name: Bayer ADVIA Centaur HER-2/ neu assay

Indications for Use:

For *in vitro* diagnostic use in the quantitative determination of the HER-2/*neu* protein in human serum using the ADVIA Centaur System. HER-2/*neu* values obtained may be used in the follow-up and monitoring of patients with metastatic breast cancer whose initial serum HER-2/*neu* level is greater than 15 ng/mL. HER-2/*neu* values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer. The clinical utility of the measurement of HER-2/*neu* in serum as a prognostic indicator for early recurrence and in the management of patients on immunotherapy has not been fully established. This test should be used by or under the order of a physician. This assay is not intended for use on any other system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. P. Reeves for J. C. Bantista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024017

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)