FEB - 8 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Valproic Acid Method for ADVIA® 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: K042807 (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure the antiepileptic drug valproic acid in human serum and plasma on the Bayer ADVIA® IMS systems. Measurements of valproic acid are used to aid in monitoring therapeutic levels of valproic acid to ensure appropriate therapy and in the treatment of valproic acid overdose.

2. Predicate Device

Product Name	Reagent Ref #	Calibrator Ref #
Bayer Centaur Valproic Acid	03783810 (129219)	02700784 (129221)

3. Device / Method

Product Name	Reagent Ref #	Calibrator Ref #
ADVIA IMS Valproic Acid	00329833	00419360

4. Performance

A. Minimum Detectable Concentration

Method	ADVIA IMS	Centaur
MDC	0.57 µg/mL	1.0 µg/mL

B. Imprecision

ADVIA IMS	
Level µg/mL	Total CV (%)
34.03	4.4
70.16	2.9
98.86	2.0

Bayer Centaur	
Level µg/mL	Total CV(%)
22.8	6.9
64.6	6.1
102.7	6.4

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx µg/mL	R	IMS Sample Range µg/mL
Serum	Centaur	50	Y= 0.98X + 4.9	3.1	0.997	13.4 - 144

D. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Valproic acid Concentration µg/mL	Effect (% change)
Bilirubin (unconjugated)	25	112.01	-3.3
Bilirubin (conjugated)	25	108.71	2.3
Hemoglobin	600	107.13	3.1
Lipids (Triglycerides)	750	102.67	9.8

E. Analytical Range

0. 57µg/mL up to valproic acid concentration in highest calibrator (Level 6) (approximately 150 µg/mL).

10/4/04

Date

Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York, 10591 - 5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 8 2005

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer Healthcare, LLC.
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

Re: k042807
Trade/Device Name: ADVIA® IMS Valproic Acid Method
ADVIA® IMS Valproic Acid Calibrator
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: LEG, DKB
Dated: October 4, 2004
Received: October 13, 2004

Dear Mr. Holle:

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

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 (240)276-0484. 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042807

Device Name: ADVIA® IMS Valproic Acid Calibrator

Indications For Use:

The *Bayer ADVIA IMS Valproic Acid calibrator* is for in vitro diagnostic use in the calibration of valproic acid using the ADVIA® IMS system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042807

Indications for Use

510(k) Number (if known): K042807

Device Name: ADVIA® IMS Valproic Acid Method

Indications For Use:

The *Bayer ADVIA IMS Valproic Acid method* is for in vitro diagnostic use to measure the antiepileptic drug valproic acid in human serum and plasma. Measurements of valproic acid (2-propylpentanoic acid) are used as an aid in the diagnosis and treatment of valproic acid overdose, and in monitoring therapeutic levels of valproic acid to ensure appropriate therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

K042807