DEC 2 4 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Ammonia method for ADVIA® 1650™

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: K023841

1. Intended Use

The *Bayer ADVIA 1650* Ammonia assay is an *in vitro* diagnostic device intended to quantitatively measure Ammonia levels in human plasma (heparin or EDTA).

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Roche Ammonia	1877984	166570

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
Bayer ADVIA® 1650™ Ammonia	B01-4822-01	B03-4827-01

Imprecision

ADVIA 1650	
Level (ug/dL)	Within-run CV(%)
69.7	3.8
150.6	1.7
387.9	0.7

Roche	
Level (ug/dL)	Within-run CV(%)
67.5	3.9
496.8	0.7
574.8	7.33

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen Type	Comparison System (x)	N	Regression Equation	Syx	r	Sample Range µg/dL
Plasma	Roche (On Hitachi)	94	Y = 1.05x + 7.19	62.18	0.98	26 - 1174

Interfering Substances

METHOD	Sample Concentration	Interferent	Interferent Concentration (mg/dL)	Sample+Interferent Concentration	Recovery %
Ammonia	179.28	hemoglobin	**250**	188.57	105.18%
	176.71	bilirubin conj	**18.75**	168.4	95.30%
	168.25	bilirubin unconj	**25**	169.05	100.48%
	214.24	Intralipid	**62.5**	195.08	91.06%
	187.56	TRIG Concentrate	**62.5**	204.4	108.98%

Analytical Range
Serum/Plasma(Lithium heparin): 25 to 1300 ug/dL

11-15-02

Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 4 2002

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k023841
Trade/Device Name: Ammonia Assay and Calibrator for the ADVIA® 1650™
Regulation Number: 21 CFR 862.1065
Regulation Name: Ammonia test system
Regulatory Class: Class II
Product Code: JIF; JIT
Dated: November 15, 2002
Received: November 18, 2002

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 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).

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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023841

Device Name: Ammonia Assay and Calibrator for the ADVIA® 1650™

Indications for Use:

The *Bayer ADVIA 1650* Ammonia method and calibrator is an *in vitro* diagnostic device intended to quantitatively measure ammonia levels in human plasma (heparin or EDTA). Such measurements are used in assessing hepatic function and diagnosis of Reye's syndrome.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023841

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)