JUL 1 3 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Ammonia method for ADVIA® 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: K021151

1. Intended Use

The *Bayer ADVIA IMS* Ammonia (NH_3) assay is an *in vitro* diagnostic device intended to measure Ammonia in human plasma (K_3EDTA). Measurements of ammonia are used as an aid in the diagnosis and treatment of several hepatic diseases such as cirrhosis, hepatic failure, hepatitis and Reye's syndrome.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Sigma Ammonia	171-C	171- C

3. Device / Method

Product Name	Reagent BAN	Calibrator BAN
Bayer ADVIA® IMS™ Ammonia	04454764	08648547

Imprecision

ADVIA IMS	
Level (umol/L)	Total CV(%)
21.4	15.8
112	3.5
234	4.3

Sigma	
Level (umol/L)	Total CV(%)
52.9	4.2
323	1.7
490	1.8

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (umol/L)	R	Sample Range (umol/L)
Plasma (K_3EDTA)	Sigma/Fara II	51	Y=0.93X+14.8	9.7	0.998	13.0 to 500

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Ammonia Conc (umol/L)	Effect (% change)
Bilirubin (unconjugated)	18.8	100	-8.0
Bilirubin (conjugated)	25	100	+3.0
Hemoglobin	500	100	+11.0
Lipids (Triglycerides)	500	100	-12.0

Analytical Range

Plasma: 5 – 500 umol/L

4. Conclusion

Performance for the ADVIA IMS Ammonia Assay on the *Bayer ADVIA*® IMS™ is equivalent to the performance of the Ammonia Assay on the predicate device (Sigma, K760332) and is within proposed manufacturing specifications. No safety and effectiveness issues have been raised.

4/8/02

Date

Kenneth T. Edds
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

JUL 13 2002

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

Re: k021151
Trade/Device Name: Ammonia Assay for the ADVIA® IMS™
Regulation Number: 21 CFR 862.1065
Regulation Name: Ammonia test system
Regulatory Class: Class I, reserved
Product Code: JIF
Dated: June 26, 2002
Received: June 27, 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: K021151

Device Name: Ammonia Assay for the ADVIA® IMS™

Indications for Use:

The *Bayer ADVIA IMS* Ammonia method is an *in vitro* diagnostic device intended to measure ammonia levels in human plasma. Such measurements are used in the diagnosis and treatment of several hepatic diseases such as cirrhosis, hepatic failure, hepatitis and Reye's syndrome.

Susan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021151

(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)