MAR 1 8 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Uric Acid 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: K022096 (leave blank)

1. Intended Use

The *Bayer ADVIA IMS* Uric Acid (UA) method is an *in vitro* diagnostic device intended to measure uric acid in human serum, plasma and urine. Such measurements are used as an aid in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation and other wasting conditions and of patients receiving cytotoxic drugs.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
ADVIA 1650 Uric Acid	B01-4131-01	T03-1291-62

3. Device / Method

Product Name	Reagent BAN #	Calibrator BAN #
ADVIA IMS Uric Acid	07383256	06798711

A. Imprecision (serum)

ADVIA IMS	
Level (mg/dL)	Total CV (%)
3.7	2.3
7.7	1.6
9.9	1.1

Advia 1650	
Level (mg/dL)	Total CV(%)
3.9	1.9
8.6	1.6
10.0	2.3

Imprecision (urine)

ADVIA IMS	
Level (mg/dL)	Total CV (%)
20.2	5.2
28.9	3.6
38.4	2.6

Advia 1650	
Level (mg/dL)	Total CV (%)
12.4	2.3
23.9	5.2

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

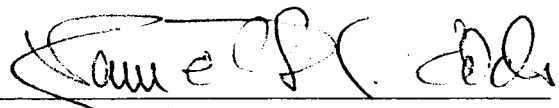
Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	CDC Uricase	117	Y=0.98X+0.11	0.27	0.999	1.5-26.2
Serum	Advia 1650	100	Y=0.96X+0.29	0.37	0.998	1.5-23.6
Plasma (y), Serum (x)	Advia 1650	54	Y=1.01X-0.05	0.08	0.998	2.8-7.3
Urine	CDC Uricase	10	Y=1.035X-0.37	1.11	0.999	3.8-182.8
Urine	Advia 1650	63	Y=0.96X-1.08	2.70	0.998	5.7-198.7

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Uric Acid Conc. (mg/dL)	Effect (% change)
Bilirubin (unconjugated)	30	7.6	-5
Bilirubin (conjugated)	30	7.6	-6
Hemoglobin	750	7.5	-7
Lipids (Intralipid)	1000	7.0	-1
Acetaminophen	280 µg/mL	20.9	-5
Ascorbic Acid	200	21.1	-5
Salicylate	500	21.3	-5

Analytical Range (serum): 0-26 mg/dL

Analytical Range (urine): 0-230 mg/dL



6/21/02

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

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 8 2003

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

Re: k022096
Trade/Device Name: Uric Acid Assay for the ADVIA Integrated Modular System (IMS)
Regulation Number: 21 CFR § 862.1775
Regulation Name: Uric acid test system
Regulatory Class: I
Product Code: KNK
Dated: January 17, 2003
Received: January 21, 2003

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). 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.

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,

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: K022096

Device Name: Uric Acid Assay for the ADVIA IMS

Indications for Use:

The *Bayer ADVIA IMS* Uric Acid (UA) method is an *in vitro* diagnostic device intended to measure uric acid in human serum, plasma and urine. Such measurements are used as an aid in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation and other wasting conditions and of patients receiving cytotoxic drugs.

(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)

Carol C Benson for Jean Cooper, DVM
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022096