JUL 11 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Salicylate 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: K020794

1. Intended Use

This *in-vitro* diagnostic method is intended to measure salicylate in human serum and plasma (lithium heparin as the anticoagulant) on ADVIA IMS. Measurements of salicylate are used in the diagnosis, monitoring and treatment of salicylate toxicity and overdose.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Abbott/TDx Salicylate	953369	953302

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
Bayer ADVIA IMS Salicylate	08319802	04120475

Imprecision (Serum)

ADVIA IMS	
Level (mg/dL)	Total CV(%)
4.8	9.6
32.1	2.7
64.6	2.5

Abbott/TDx	
Level (mg/dL)	Total CV(%)
7.5	4.48
30	2.95
60	2.98

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	Abbott/TDx	47	Y=0.997X - 1.39	2.88	0.996	0.5-112.2
Plasma(y), Serum(x)	ADVIA IMS	49	Y=0.985X + 0.00	2.73	0.988	4.2-75.8

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Salicylate Conc (mg/dL)	Effect (% change)
Bilirubin (unconjugated)	25	29.6	0.0
Bilirubin (conjugated)	25	31.9	0.0
Hemoglobin	1000	29.7	+6.0
Lipids (Triglycerides)	500	29.1	+7.0

Analytical Range
Serum/Plasma: 0 to 120 mg/dL

4. Conclusion

Performance of the ADVIA IMS Salicylate Assay on a *Bayer ADVIA*® IMS™ is equivalent to the performance of the Salicylate Assay on the predicate device (Abbott TDX, K844070) and is within proposed manufacturing specifications. No safety and effectiveness issues have been raised.

Kenneth T. Edds — Date: 2/28/02

Kenneth T. Edds
Manager 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

JUL 11 2002

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

Re: k020794
Trade/Device Name: Salicylate Assay for the ADVIA® IMS™
Regulation Number: 21 CFR 862.3830
Regulation Name: Salicylate test system
Regulatory Class: Class II
Product Code: DKJ
Dated: June 19, 2002
Received: June 20, 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: K020794

Device Name: Salicylate Assay for the ADVIA® IMS™

Indications for Use:
The *Bayer ADVIA IMS* Salicylate method is an *in vitro* diagnostic device intended to measure salicylate levels in human serum or plasma (Lithium heparin). Such measurements are used in the diagnosis of salicylate toxicity and overdose.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020794

(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)