OCT 1 1 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Glucose methods 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: K052163

1. Intended Use

The Bayer ADVIA IMS® Glucose assay is an in vitro diagnostic device for use to measure glucose in human serum, plasma, urine and cerebrospinal fluid (CSF) on the ADVIA IMS® System. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and neonatal hypoglycemia.

2. Assay Principle

The ADVIA IMS® Glucose method is based on the combination of hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6PD) for the specific measurement of glucose in serum, plasma, urine and cerebral spinal fluid.

3. Predicate Device

Product Name	Reagent Ref #	Calibrator Ref #
Bayer ADVIA® 1650 Glucose Hexokinase II	04903429	09784096

4. Device / Method

Product Name	Reagent Ref #	Calibrator Ref #
Bayer ADVIA IMS® Glucose	08594722	09784096

5. CSF Imprecision

ADVIA IMS Glucose			ADVIA 1650 Glucose Hexokinase II		
Level (mg/dL)	Within-run CV (%)	Total CV (%)	Level (mg/dL)	Within-run CV(%)	Total CV (%)
36	2.1	2.3	31	1.6	2.7
60	2.1	2.2	59	1.8	3.1

6. CSF Correlation (X=ADVIA 1650, Y=ADVIA IMS)

N	Regression Equation	Syx	r	Sample Range mg/dL
64	Y = 0.92x + 2.3	1.9	0.997	31-132

7. Interfering Substances

Interfering substances are not expected in cerebrospinal fluid samples.

8. Analytical Range

1 mg/dL - 600 mg/dL

9. Minimum Detectable Concentration

1 mg/dL

_____ ___10/05/2005_____

Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097
Tel: 914-524-3494

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 1 2005

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k052163
Trade/Device Name: Glucose assay for the ADVIA IMS® System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: August 31, 2005
Received: September 1, 2005

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 (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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K052163

Device Name: Glucose assay for the ADVIA IMS® System

Indications For Use:

The *Bayer ADVIA IMS®* Glucose method is for *in vitro* diagnostic device for use to measure glucose in human serum, plasma (lithium heparin), urine and cerebrospinal fluid (CSF) on the ADVIA IMS® system. Such measurements are used as an aid in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders including diabetes mellitus and neonatal hypoglycemia.

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) K052163