SEP 2 9 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Glucose methods 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: K042015

1. Intended Use

The Bayer ADVIA 1650 Glucose Oxidase and Glucose Hexokinase II assays are in vitro diagnostic devices intended to quantitatively measure glucose levels in human cerebrospinal fluid (CSF), serum, plasma, and urine on the ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglcemia, idiopathic hypoglycemia and insulin overdose.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Roche Glucose Hexokinase	20763020	10759350

3. Device / Method

Product Name	Reagent Part #/ BAN #	Calibrator Part #/ BAN #
Bayer ADVIA® 1650 Glucose Hexokinase	B01-4597-01/ 04005536	T03-1291-62/ 09784096
Bayer ADVIA® 1650 Glucose Oxidase	B01-4130-01/ 04903429	T03-1291-62/ 09784096

Imprecision

ADVIA 1650 Glucose Oxidase		ADVIA 1650 Glucose Hexokinase II		Roche Glucose Hexokinase	
Level (mg/dL)	Within-run CV(%)	Level (mg/dL)	Within-run CV(%)	Level (mg/dL)	Within-run CV(%)
58.0	1	60.2	1.2	31	1.6
34.2	1.1	36.9	1.7	59	1.8

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

Specimen Type	Comparison System (x)	N	Regression Equation	Syx	r	Sample Range mg/dL
Glucose (Oxidase)	Roche (On Integra)	56	Y = 0.97x + 4.47	7.6	0.994	37-530
Glucose (Hexokinase)	Roche (On Integra)	55	Y = 1.03x – 1.25	6.4	0.987	39-214

Interfering Substances

Interfering substances are not expected in cerebrospinal fluid samples.

Analytical Range

Glu-HKII: 0- 700 mg/dL
Glu-Ox: 0- 750 mg/dL

7/20/04

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

SEP 29 2004

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

Re: k042015
Trade/Device Name: Glucose Hexokinase II assay for the ADVIA® 1650 Chemistry System
Glucose Oxidase assay for the ADVIA® 1650 Chemistry System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CFR
Dated: July 15, 2004
Received: August 5, 2004

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

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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): K042015

Device Name: Glucose Hexokinase II assay for the ADVIA® 1650 Chemistry System

Indications For Use:

The *Bayer ADVIA® 1650* Glucose Hexokinase II assay is an *in vitro* diagnostic device for use in the quantitative determination of glucose in human cerebrospinal fluid (CSF), serum, plasma (lithium heparin), and urine on the ADVIA® 1650 Chemistry system. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and insulin overdose.

Prescription Use ✓ 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) K042015

Indications for Use

510(k) Number (if known): K042015

Device Name: Glucose Oxidase assay for the ADVIA® 1650 Chemistry System

Indications For Use:

The *Bayer ADVIA® 1650* Glucose Oxidase assay is an *in vitro* diagnostic device for use in the quantitative determination of glucose in human cerebrospinal fluid (CSF), serum, plasma and urine on the ADVIA® 1650 Chemistry system. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and insulin overdose.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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