MAR - 7 2011

510(k) Summary of Safety and Effectiveness for the

ADVIA® 1650 Chemistry Glucose Hexokinase_3 (GLUH_3) method

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k101854

B. Date of Preparation: July 26, 2010

C. Proprietary and Established Names:

ADVIA® 1650 Chemistry Glucose Hexokinase_3 (GLUH_3) reagent

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Kira Gordon, Sr. Regulatory Affairs Specialist

Office: (914) 524-2996 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA 1650 Chemistry Glucose Hexokinase_3 Reagent

1. Regulation section: 21 CFR § 862.1345 Glucose test system.

2. Classification: Class II

3. Product Code: CFR, Hexokinase, Glucose

4. Panel: Clinical Chemistry

F. Predicate Device:

ADVIA 1650 Chemistry Glucose Hexokinase_3 reagent is substantially equivalent to the ADVIA Chemistry Glucose Hexokinase II reagent cleared under k042015

G. Device Description:

The ADVIA 1650 Chemistry Glucose Hexokinase_3 (GLUH_3) method uses a two-component reagent. Sample is added to Reagent 1, which contains the buffer, ATP, and NAD. Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Reagent 2 is added, which initiates the conversion of glucose and the development of absorbance at 340/410 nm. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

H. Intended Use:

For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF 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

I. Substantial Equivalence Information:

The new device (Glucose Hexokinase_3 reagent) and the predicate device (Glucose Hexokinase II reagent) were compared. A comparison of the important features between the new device and the predicate device is provided in the following table:

Item	Device	Predicate
Analyte	Glucose	Same
Intended Use	For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF 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	Same
Sample type	human serum, plasma, urine and CSF (plasma – Li Heparin and K EDTA)	human serum, plasma, urine and CSF (plasma – Li Heparin)
Instrument to be used	ADVIA 1650 Chemistry	ADVIA 1650 Chemistry
Method Principle	based on the method by Slein using hexokinase and glucose-6-phosphate dehydrogenase enzymes.	Same
Calibrators	Siemens Healthcare Diagnostics Chemistry Calibrator REF 09784096	Same
Reportable range	4 -700 mg/dL	0 -700 mg/dL
Traceability	Standard reference material 965a from NIST	Same
Format	Liquid	Concentrate
Reagents	Two: R1 and R2	Three: R1, R2 and R2 mix
Interfering Substances *	Bilirubin–NSI to 30 mg/dL at glucose level of 54 mg/dL Hemoglobin–NSI up to 1000 mg/dL at glucose level of 52 mg/dL Lipemia (Intralipid)–NSI to 1000 mg/dL at glucose level of 53 mg/dL	Bilirubin–NSI to 25 mg/dL at glucose level of 80 mg/dL Hemoglobin–NSI up to 500 mg/dL at glucose level of 80 mg/dL Lipemia (Intralipid)–NSI to 500 mg/dL at glucose level of 80 mg/dL

Precision (total)	0.8% at 87 mg/dL (serum) 0.7% at 297 mg/dL (serum) 1.1% at 49 mg/dL (urine) 1.9% at 301 mg/dL (urine) 1.0% at 56 mg/dL (CSF) 0.8% at 97 mg/dL (CSF)	2.2% at 74.7 mg/dL (serum) 2.0% at 247.6 mg/dL (serum) 4.1% at 45.8 mg/dL (urine) 3.6% at 266.7 mg/dL (urine) 3.1% at 36.9 mg/dL (CSF) 2.7% at 60.2 mg/dL (CSF)
Accuracy / Correlation	Serum: Y = 1.001x + 0.3; N=99 r=1.000 (vs. ADVIA 1650 (ADVIA GLUH reagent) Plasma (Li-Heparin): Y = 1.001x + 0.2, N=88; r=1.000 Plasma (K-EDTA) Y = 1.002x – 0.0, N=87; r=1.000 CSF: Y = 1.005x – 0.1, N=113; r=1.000 Urine: Y = 0.989x – 0.3, N=51; r=1.000	Serum: Y = 1.02x – 1.84; N=194 r=0.998 (vs. ADVIA 1650 (ADVIA glucose-single reagent formulation)) Plasma (Li Heparin): Y = 1.00x - 0.09, N=35; r=1.000 CSF: Y = 1.03x – 1.25, N=55; r=0.987 Urine: Y = 0.97x – 7.44, N=99; r=0.999

* NSI = No Significant Interference. A percentage effect > 10% is considered significant interference.

J. Conclusion:

Comparative testing of the ADVIA 1650 Chemistry Glucose Hexokinase_3 reagent demonstrates substantially equivalent performance to the ADVIA Chemistry Glucose Hexokinase II reagent cleared under K042015.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAR 0 7 2011

Siemens Healthcare Diagnostics, Inc.
c/o Kira Gordon
Senior Regulatory Affairs Specialist
511 Benedict Avenue,
Tarrytown, NY, 10591, USA

Re: k101854
Trade/Device Name: ADVIA Chemistry Glucose Hexokinase (GLUH_3) Reagent
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CFR
Dated: February 23, 2011
Received: February 24, 2011

Dear Ms. Gordon

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K101854

Device Name:

ADVIA® Chemistry GLUH_3 Reagent

Indication For Use:

For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF 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 ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101854