510(k) Summary

MAY - 5 2006

Submitter's Name/Address
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Date of Preparation of this Summary:	February 13, 2006
Device Trade or Proprietary Name:	Glucose
Device Common/Usual Name or Classification Name:	Glucose
Classification Number/Class:	CFR/Class II

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.

The assigned 510(k) number is: K060383

Test Description:

The Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF). Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD) to nicotinamide adenine dinucleotide reduced (NADH). One micromole of NADH is produced for each micromole of glucose consumed. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Substantial Equivalence:

The Glucose assay is substantially equivalent to the Glucose/HK assay (K953847) on the Hitachi 917 Analyzer. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro enzymatic chemical reaction assays.
- Both assays can be used for the quantitative analysis of glucose.
- Both assays yield similar results.
- Both assays are based on the hexokinase/G-6-PDH methodology.

Differences:

None

Intended Use:

The Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF).

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® and ARCHITECT® *c*8000® Systems. The Glucose assay method comparison yielded acceptable correlation with the Glucose/HK assay on the Hitachi 917 Analyzer. The AEROSET System showed a correlation coefficient of 0.9995, slope of 1.09, and Y-intercept of – 5.50 mg/dL for the serum application, a correlation coefficient of 0.9998, slope of 1.09, and Y-intercept of - 1.35 mg/dL for the urine application, and a correlation coefficient of 0.9998, slope of 1.09, and Y-intercept of - 4.29 mg/dL for the CSF application when compared to the Hitachi 917 Analyzer. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9993, slope of 1.06, and Y-intercept of - 4.54 mg/dL for the serum application, a correlation coefficient of 0.9998, slope of 1.04, and Y-intercept of –2.67 mg/dL for the urine application, and a correlation coefficient of 0.9997, slope of 1.04, and Y-intercept of –3.89 mg/dL for the CSF application when compared to the Hitachi 917 Analyzer. The ARCHITECT c8000 System showed a correlation coefficient of 0.9996, slope of 0.97 and Y-intercept of 0.85 mg/dL for the serum application, a correlation coefficient of 0.9999, slope of 0.96, and Y-intercept of -1.36 mg/dL for the urine application, and a correlation coefficient of 0.9998, slope of 0.95, and Y-intercept of 0.22 mg/dL for the CSF application when compared to the AEROSET System. The Glucose assay method comparison yielded acceptable correlation between the AEROSET System and the ARCHITECT *c*8000 System.

Precision studies were conducted using the Glucose assay. On the AEROSET System, the total %CV for Level 1 is 1.06%, and Level 2 is 1.41% for the serum application, the total %CV for Level 1 is 1.66%, and Level 2 is 1.35% for the urine application, and the total %CV for Level 1 is 1.55%, and Level 2 is 1.69% for the CSF application. On the ARCHITECT *c*8000 System, the total %CV for Level 1 is 2.15%, and Level 2 is 1.51% for the serum application, the total %CV for Level 1 is 1.01%, and Level 2 is 0.80% for the urine application, and the total %CV for Level 1 is 1.07%, and Level 2 is 1.17% for the CSF application.

The Glucose assay is linear from 5 to 800 mg/dL for the serum/plasma application. The Glucose assay is linear from 1 to 800 mg/dL for the urine/CSF application. The limit of quantitation (sensitivity) of the Glucose assay is 5.0 mg/dL for the serum application, and 1.0 mg/dL for the urine/CSF applications.

These data demonstrate that the performance of the Glucose assay is substantially equivalent to the performance of the Glucose/HK assay on the Hitachi 917 Analyzer.

Conclusion:

The Glucose assay is substantially equivalent to the Glucose/HK assay on the Hitachi 917 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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MAY - 5 2006

Re: k060383
Trade/Device Name: Glucose test system
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: February 13, 2006
Received: February 22, 2006

Dear Ms. Morris:

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,

Alberto Gutierrez, Ph.D.
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): K060383

Device Name: Glucose

Indications For Use:

A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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