K061048

510(k) Summary – COBAS INTEGRA Glucose HK Gen. 3

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
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Contact person: Corina Harper

Date prepared: April 11, 2006

Device Name

Proprietary name: COBAS INTEGRA Glucose HK Gen. 3 test

Common name: Glucose HK Gen. 3

Classification name: Glucose Test System

Device Description

The cassette COBAS INTEGRA Glucose HK Gen. 3 contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA SYSTEMS for the quantitative determination of glucose in serum, plasma, urine, and cerebrospinal fluid (CSF).

The test principle is an enzymatic reference method with hexokinase.

Intended use

In vitro test for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid (CSF) on COBAS INTEGRA systems.

Predicate Device

We claim substantial equivalence to the COBAS INTEGRA Glucose HK Liquid cleared as K972250.

Substantial equivalency – Similarities

The table below indicates the similarities between the modified COBAS INTEGRA Glucose HK Gen. 3 test and its predicate device (COBAS INTEGRA Glucose HK Liquid, K972250).

Feature	Predicate device: Glucose HK Liquid (K972250)	Modified device: Glucose HK Gen. 3
General		
Intended Use/ Indications for Use	The cassette COBAS INTEGRA Glucose HK Liquid contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of glucose concentration in serum, plasma, urine and cerebrospinal fluid (CSF).	In vitro test for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid (CSF) on COBAS INTEGRA systems
Specimen type	Serum, plasma, urine, CSF	Same
Test principle		
Reference method	Enzymatic reference method with hexokinase.	Same
Reagent information		
Stability - shelf life and on-board	2-8 °C until expiration date COBAS INTEGRA 400 8 weeks at 10 to 15° C COBAS INTEGRA 700/800 8 weeks at 8°C	Same
Calibrator	Calibrator f.a.s. Interval: each lot	Same
Quality control	<u>Serum and plasma</u>: Precinom U and Precinorm U Plus Precipath and Precipath U Plus <u>Urine:</u> Quantitative urine controls <u>CSF:</u> Quantitative CSF controls Interval: 24 hrs recommended	Same
Traceability	Standardized against Isotope Dilution Mass Spectrometry	Same
Performance characteristics		
Measuring range	0-40 mmol/L (0-720 mg/dL) Extended measuring range with recommended post dilution factor of 10: 0-400 mmol/L (0-7200 mg/dL)	0.12-40 mmol/L (0.12-720 mg/dL) Extended measuring range with recommended post dilution factor of 10: 0.12-400 mmol/L (2.16-7200 mg/dL)

Expected values (literature reference) Additional values are referenced in the method sheet	Plasma (fasting): 3.88-6.38 mmol/L Urine: 1st morning urine 0.3-1.1 mmol/L 24 h urine 0.11-0.50 mmol/24h Serum/plasma: Adults 4.11-5.89 mmol/L	Plasma (fasting): 3.88-6.38 mmol/L Urine: 1st morning urine 0.3-1.1 mmol/L 24 h urine 0.3-0.96 mmol/L Same

Substantial equivalency – Differences

The table below indicates the similarities between the modified COBAS INTEGRA Glucose HK Gen. 3 test and its predicate device (COBAS INTEGRA Glucose HK Liquid, K972250).

Feature	Predicate device: Glucose HK Liquid (K972250)	Modified device: Glucose HK Gen.3
Reagent information		
R1 R2	Mono reagent in vial A and B (liquid) 100 mmol/L MOPS, 12 mmol/L ATP, 6 mmol/L NAD^+, 10 mmol/L Mg^{++}, ≥50 µcat/L HK(yeast), ≥50 µcat/L G6PDH (microbial), 0.09% Sodium azide, pH 7.1	R1: 5.0 mmol/L MES, ≥4.5 mmol/L ATP, 24 mmol/L Mg^{++}, ≥7.0 mmol/L NADP, pH 6.0 R2: 4.0 mmol/L Mg^{++}, 200 mmol/L HEPES, ≥300 µcat/L HK (yeast), ≥300 µcat/L G6PDH (microbial), pH 8.0
Performance characteristics		

Precision	Serum and plasma: Within run: 1.7% @ 5.3 mmol/L 0.72% @ 33.2 mmol/L Between run: 2.6% @ 5.3 mmol/L 1.5% @ 33.2 mmol/L Urine application Within run: 1.7% @ 1.7 mmol/L 1.8% @ 37.1 mmol/L Between run: 4.3% @ 1.7 mmol/L 2.9% @ 37.1 mmol/L CSF application Within run: 1.6% @ 1.7 mmol/L 1.8% @ 3.3 mmol/L Between run: 2.3% @ 1.7 mmol/L 1.9% @ 3.3 mmol/L	Serum and plasma: Within run CV%: 0.41% @ 4.48 mmol/L 0.47% @ 12.48 mmol/L Between day: 1.09% @ 4.44 mmol/L 0.90% @ 12.46 mmol/L Urine application Within run: 1.35% @ 0.83 mmol/L 0.64% @ 2.42 mmol/L Between day: 0.75% @ 0.84 mmol/L 0.83% @ 2.43 mmol/L CSF application Within run: 1.13% @ 3.20 mmol/L 1.49% @ 9.31 mmol/L
Linearity	0-40 mmol/L (before dilution)	0.12-40 mmol/L (before dilution)
Lower detection limit	Serum and plasma: 0.033 mmol/L Urine application: 0.22 mmol/L CSF application: 0.023 mmol/L	Serum, plasma, urine and CSF: 0.12 mmol/L
Endogenous interferences	Hemolysis no significant interferences Icterus no significant interferences Lipemia no significant interferences	Hemolysis: up to 1200 H Index Icterus: up to 60 I Index Lipemia: up to 1900 L Index

Exogenous Interferences	Falsely low results may be caused by elevated pyruvates levels Gammopathy, in particular IgM, may cause unreliable results in rare cases	Tetracyclin at therapeutic concentration gives falsely low results in urine samples Same

Proposed Labeling

Proposed labeling sufficient to describe the device, its intended use, and the directions for use can be found in Section V. We believe the proposed version of the device labeling presented contains all of the technical information required per 21 CFR 809.10.

Validation and Design Control

Development activities were conducted under appropriate design control procedures and the overall product specifications were met. The Declaration of Conformity with Design Controls and Results of Risk Analysis are provided in Section 5.1. Analytical Performance.

Confidentiality

Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of this submission until the substantial equivalence decision has been reached.

Closing

Modification of the COBAS INTEGRA Glucose HK Gen.3 does not affect the intended use or indications for use of the device as described in the labeling, nor does it alter the fundamental scientific technology of the device. Therefore, we trust the information provided in this Special 510(k) will support a decision of substantial equivalence of the COBAS INTEGRA Glucose HK Gen.3 to the predicate.

If you have any questions or require further information, please do not hesitate to contact this office.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAY 17 2006

Re: k061048
Trade/Device Name: COBAS INTEGRA Glucose HK Gen 3
Regulation Number: 21 CFR§ 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: April 14, 2006
Received: April 17, 2006

Dear Ms. Harper:

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): K061048

Device Name: COBAS INTEGRA Glucose HK Gen 3

Indications For Use:

In vitro test for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid (CSF) on COBAS INTEGRA systems.

Glucose measurements are used in diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and pancreatic islet cell tumors.

Prescription Use **XXXX** 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 Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061048