K071211

JUL 30 2007

510(k) Summary

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.

Submitter name, address, contact

Roche Diagnostics Operations
9115 Hague Road
Indianapolis, IN 46250
317-521-3831

Contact Person: Corina Harper

Date Prepared: April 2007

Device name

Proprietary name: **cobas c** 111 Analyzer

Common name: Analyzer, Chemistry (Photometric, Discrete), for clinical use

Classification name: Discrete photometric chemistry analyzer for clinical use

Establishment information

The establishment registration number for Roche Diagnostics Ltd. is 3003795116.

The establishment registration number for Roche Diagnostics GmbH is 9610126.

The establishment registration number for Roche Diagnostics Corporation is 1823260.

Classification

The FDA has classified a discrete photometric analyzer in Class I.

Panel	Classification Number	Classification Name	Regulation Citation
75 Clinical Chemistry	1	Discrete photometric chemistry analyzer for clinical use	21 CFR 862.2160

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Performance standards

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Submission history

The **cobas c**111 analyzer is a member of the COBAS INTEGRA® family of analyzers cleared in the Total Bilirubin reagent submission as K063744. The reagents applied to this analyzer are cleared reagents for the COBAS INTEGRA family of analyzers and were successfully applied to the **cobas c** 111 analyzer using the *Replacement Reagent and Instrument Family Policy* – Dec 11, 2003, to demonstrate equivalence to the original reagent/instrument performance.

Device modification – Additional indication for cobas c 111 **analyzer**

The table below compares the additional intended use for the device, **cobas c** 111 analyzer to the current device, **cobas c** 111 for professional use.

Topic	**cobas c** 111 **Analyzer professional use (K063744)**	**cobas c** 111 **Analyzer with extended intended use**
Analyzer Description		
Intended Use/Indications of Use	The Roche **cobas c** 111 analyzer is an *in-vitro* diagnostic analyzer capable of performing clinical chemistry, specific protein and electrolyte tests. Analytes are measured photometrically or turbidimetrically; the analyzer also has an optional ISE module for measuring sodium, potassium and chloride.	The Roche **cobas c** 111 analyzer is an *in-vitro* diagnostic analyzer capable of performing clinical chemistry, specific protein and electrolyte tests in the professional setting and small laboratories, specialized testing and CLIA-licensed doctor's offices. Analytes are measured photometrically or turbidimetrically; the analyzer also has an optional ISE module for measuring sodium, potassium and chloride

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Device modifications – reagents comparison

The following table compares the panel of six assays performance characteristics on cobas c 111 analyzer for professional use with the point-of-care use.

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Intended Use for representative reagents	AST: In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum and plasma on the **cobas c** 111 system. Glucose: In vitro test for the quantitative determination of glucose in human serum and plasma on the **cobas c** 111 system. CRP: In vitro test for the quantitative determination of C-reactive protein in human serum and plasma on the **cobas c** 111 system. ISE-Cl: The chloride electrode for the **cobas c** 111 system is intended for the quantitative determination of chloride in diluted serum, plasma and urine. ISE-K: The potassium electrode for the **cobas c** 111 system is intended for the quantitative determination of chloride in diluted serum, plasma and urine. ISE-Na: The sodium electrode for the **cobas c** 111 system is intended for the quantitative determination of chloride in diluted serum, plasma and urine.	Same
Instrument	**cobas c** 111 analyzer	Same
Operator	Professional setting	Point-of-care setting
Sample type	AST: serum and plasma Glucose: serum and plasma CRP: serum and plasma ISE-Cl: serum, plasma and urine ISE-K: serum, plasma and urine ISE-Na: serum, plasma and urine	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Traceability/ Standardization	AST: standardized against the original IFCC formulation using calibrated pipettes together with manual photometer providing absolute values and the substrate-specific absorptivity, ε Glucose: standardized against ID/MS CRP: standardized against the reference preparation of the IRMM – BCR470/ CRM470 (RPPHS – Reference Preparation for Proteins in Human Serum) ISE-Cl/K/Na: standardized against primary calibrators prepared gravimetrically from purified salts	Same
Measuring range	AST: 2-700 U/L Glucose: 0.11-40 mmol/L CRP: 1-200 mg/L ISE-Cl: 20-250 mmol/L ISE-K: 1-100 mmol/L ISE-Na: 20-250 mmol/L	Same
Analytical sensitivity (LDL)	AST: 2 U/L Glucose: 0.11 mmol/L CRP: 1.0 mg/L ISE-Cl: slope range -25 to -56 mV/dec ISE-K: slope range 45 to 63 mV/dec ISE-Na: slope range 45 to 63 mV/dec	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Precision Within run (CV%/SD)	AST Human Sera : SD 0.37 at 26.2 U/L 0.5% at 221 U/L	 Human sera: SD 0.78 at 18.98 U/L 2.07 % at 46.92 U/L
	Controls: 1.1% at 39.7 U/L 0.4% at 123 U/L	Controls: 1.99% at 41.05 U/L 0.63% at 137.93 U/L
	Glucose Human Sera: SD 0.5 at 40.9 mg/dL 0.8% at 180 mg/dL	 Human sera: 0.56% at 89.14 mg/L 0.63% at 168.29 mg/L
	Controls: 1.0% at 90.6 mg/dL 0.5% at 252 mg/dL	Controls: 0.63% at 96.11 mg/L 0.66% at 255.47 mg/L
	CRP Human Sera: SD 0.01 at 0.42 mg/dL 1.3% at 23.4 mg/dL	 Human sera: SD 0.072 at 0.356 mg/dL 1.15%-- 0t 0.554 mg/dL 1.23% at 2.385 mg/dL
	Controls: 0.8% at 1.83 mg/dL 0.6% at 3.77 mg/dL	Controls: 0.68% at 0.842 mg/dL 0.41% at 4.792 mg/dL
	ISE – Cl Human Sera: 0.30% at 97 mmol/L 0.24% at 1.27 mmol/L	 Human sera: 0.72% at 109.03 mmol/L 0.72% at 98.55 mmol/L
	Plasma: 0.29% at 93 mmol/L 0.24% at 124 mmol/L	Controls: SD 0.43 at 86.22 mmol/L 0.54% at 119.04 mmol/L

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Precision Within run (CV%)	ISE - K Human Sera: 0.49% at 2.1 mmol/L 0.40% at 5.7 mmol/L	 Human sera: 0.79% at 4.65 mmol/L 0.71% at 4.69 mmol/L
	Plasma: 0.41% at 2.0 mmol/L 0.32% at 60. mmol/L	Controls: 0.47% at 3.465 mmol/L SD 0.040 at 6.621mmol/L
	ISE – Na Human Sera: 0.32% at 130 mmol/L 0.31% at 156 mmol/L	 Human sera: 0.59% at 144.69 mmol/L 0.61% at 133.70 mmol/L
	Plasma 0.31% at 127 mmol/L 0.30% at 151 mmol/L	Controls: 0.39% at 126.66 mmol/L 0.41% at 150.50 mmol/L
Precision Total (CV%/SD unit)	AST Human Sera: SD 0.64 at 19.5 U/L 1.0% at 306 U/L	 Human sera: SD 1.2 at 16.4 U/L 3.7% at 48.7 U/L
	Controls: 2.4% at 38.6 U/L 0..9% at 126 U/L	Controls: 3.3% at 40.24 U/L 2.2% at 137.04 U/L
	Glucose Human Sera: SD 0.2 at 45.4 mg/dL 0.6% at 178 mg/dL	 Human sera: 2.6% at 97.5 mg/L 2.8% at 130.7 mg/L
	Controls: 0.7% at 92.3 mg/dL 0.5% at 254 mg/dL	Controls: 2.5% at 93.03 mg/L 2.5% at 247.08 mg/L

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Precision Total (CV%/SD unit)	CRP Human Sera: SD 0.01 at 0.47 mg/dL 2.6% at 2.33 mg/dL	Human sera: 3.7% at 4.044 mg/dL 3.2% at 4.670 mg/L
	Controls: 2.1% at 1.86 mg/dL 1.6% at 3.84 mg/dL	Controls: 2.6% at 0.835 mg/dL 2.9% at 4.764 mg/dL
	ISE – Cl (Between-run) Human sera: 0.44% at 97 mmol/L 0.48% at 128 mmol/L	Human sera: 1.4% at 104.7 mmol/L 1.6% at 104.6 mmol/L
	Plasma (Between-run): 0.51% at 93 mmol/L 0.67% at 125 mmol/L	Controls: SD 2.0 at 87.16 mmol/L 2.0% at 119.97 mmol/L
	ISE – K (Between –run) Human Sera: 0.45% at 2.1 mmol/L 0.30% at 5.7 mmol/L	Human sera: 1.4% at 4.465 mmol/L 1.6% at 4.540 mmol/L
	Plasma (Between-run) 0.78% at 2.0 mmol/L 0.72% at 6.0 mmol/L	Controls: 1.8% at 3.466 mmol/L SD 1.8 at 6.646 mmol/L
	ISE – Na (Between-run) Human Sera: 0.42% at 130 mmol/L 0.48% at 155 mmol/L	Human sera: 1.6% at 139.9 mmol/L 1.6% at 131.6 mmol/L
	Plasma: 0.80% at 128 mmol/L 0.75% at 151 mmol/L	Controls: 1.8% at 126.48 mmol/L 1.7% at 151.0 mmol/L

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Limitations - interferences	AST: Bilirubin– no interference up to I index of 67 (conjugated) and I index of 65 (unconjugated) Hemolysis: elevated results with contamination of erythrocytes Lipemia: interferences Anticoagulants: citrate and fluoride interfere Glucose: Bilirubin– no interference up to I index of 67 (conjugated or unconjugated) Hemolysis: no interference up to H index of 1046 Lipemia: no interference up to L index of 2126 CRP: Bilirubin– no interference up to I index of 60 (conjugated or unconjugated) Hemolysis: no interference up to H index of 700 Lipemia: no interference up to L index of 700 Rheumatoid factors up to 1200 IU/mL do not interfere No high dose hook-effect is seen up to a CRP concentration of 3100 mg/L	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Limitations - interferences	ISE-Cl: Serum/Plasma: Hemolysis: Avoid hemolyzed samples. No significant interferences up to a hemoglobin level of 10 g/L Bilirubin/Lipemia: No significant interferences ISE-K: Serum/Plasma: Hemolysis: Avoid hemolyzed samples. No significant interferences up to a hemoglobin level of 1 g/L. Potassium centration in erythrocytes is 25 times higher than in normal plasma. The level of interference may be variable depending on the excat content of erythrocytes. Bilirubin/Lipemia: No significant interferences ISE-Na: Serum/Plasma: Hemolysis: Avoid hemolyzed samples. No significant interferences up to a hemoglobin level of 10 g/L Bilirubin/Lipemia: No significant interferences	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Endogenous interferences	AST: No interferences found using common drug panel, except: Doxycycline HCl causes artificially low results Glucose: No interferences found using common drug panel. CRP: No interferences found using common drug panel. ISE-Cl: Serum/Plasma: Panel of drugs tested causes no significant interferences Salicylic acid in concentration of 5 mmol/L causes artificially elevated results Urine: Panel of drugs tested causes no significant interferences, except: Salicylic acid, Ca-dobesilate and Na-cefoxitin which causes artificially elevated Cl concentrations ISE-K: Serum/Plasma: Panel of drugs tested causes no significant interferences up to the indicated concentration. Urine: Panel of drugs tested causes no significant interferences up to the indicated concentration.	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Endogenous interferences	ISE-Na: Serum/Plasma: Panel of drugs tested causes no significant interferences up to the indicated concentration. Urine: Panel of drugs tested causes no significant interferences up to the indicated concentration. pH – Acidified urines can give false results.	Same
Calibration frequency	AST/Glucose/CRP: Each lot and as required following quality control procedures ISE-Cl/K/Na: 24 hours (main calibration) After ISE cleaning and maintenance, changing reagent bottles, replacing electrodes	Same

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Method Comparison Professional use y = cobas c 111 x = Integra 400 Point-of-care use: y = cobas c 111 x = Integra 400	AST: Passing Bablok: y = 0.989x + 1.869 U/L τ = 0.981 n = 82 Glucose: y = 1.02x – 0.009 mmol/L τ = 0.983 n = 80 CRP: y = 0.995x + 1.334 mg/L τ = 0.970 n = 63 ISE-Cl: y = 1.014x – 3.236 mmol/L r = 0.982 n = 51 ISE-K: y = 0.984x - 0.003 mmol/L r = 1.000 n = 51 ISE-Na: y = 0.986x – 0.364 mmol/L τ = 0.983 n = 51	AST: Passing Bablok: y = 0.989x + 1.276 U/L τ = 0.8316 n = 333 Glucose: y = 0.997x + 2.069 mg/dL τ = 0.9217 n = 333 CRP: y = 1.058x + 0.022 mg/L τ = 0.9789 n = 326 ISE-Cl: y = 1.011x – 0.51 mmol/L τ = 0.7532 n = 280 ISE-K: y = 0.943x + 0.189 mmol/L τ = 0.8835 n = 280 ISE-Na: y = 1.064x – 9.818 mmol/L τ = 0.6920 n = 280

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Device modifications – reagents comparison (continued)

Feature	Reagent performance characteristics on cobas c 111 analyzer for professional use	Reagent performance characteristics for point-of-care use
Expected values (from reference) (also please reference method sheet)	AST: Female: up to 32 U/L Males: up to 38 U/L Glucose: Plasma fasting: 3.88-6.38 mmol/L Serum/Plasma Adults: 4.11-5.89 mmol/L CRP: Adults: less than 5 mg/L ISE-Cl: Serum/Plasma (adults): 98-107 mmol/L Urine (24h, adults): 110-250 mmol/L ISE-K: Serum (adults): 3.5-5.1 mmol/L Plasma (adults): 3.4-4.5 mmol/L Urine (24h, adults) 25-125 mmol/L ISE-Na: Serum (adults): 136-145 mmol/L Plasma (adults): 136-145 mmol/L Urine (24h, adults): 40-220 mmol/L	Same

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corporation
c/o Corina Harper, Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250

JUL 30 2007

Re: k071211
Trade/Device Name: cobas c 111 analyzer and applied reagents
Regulation Number: 21 CFR 862.1100
Regulation Name: Aspartate amino transferase (AST/SGO) test system
Regulatory Class: Class II
Product Code: CIT, CFR, DCN, CEM, CGZ, JGS, JJE
Dated: April 30, 2007
Received: May 1, 2007

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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): K071211

Device Name: **cobas c** 111 analyzer and applied reagents

Indications For Use:

cobas c 111 analyzer:

The Roche **cobas c** 111 analyzer is an *in-vitro* diagnostic analyzer capable of performing clinical chemistry, specific protein and electrolyte tests for professional settings and small laboratories, specialized testing and CLIA-licensed doctor's offices.
Analytes are measured photometrically or turbidimetrically; the analyzer also has an optional ISE module for measuring sodium, potassium and chloride.

Reagents:

Aspartate aminotransferase (ASTL/ASTPL)
In vitro test for the quantitative determination of AST in human serum and plasma on the cobas c111 system. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

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

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

Carol C Benson

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K071211

Indications for Use

510(k) Number (if known): K071211

Device Name: **cobas c** 111 analyzer and reagents

Indications For Use:

C-Reactive Protein Latex (CRPLX)
In vitro test for the quantitative immunological determination of human C-reactive protein in human serum and plasma on the cobas c111 system. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

Glucose HK (GLUC2)
In vitro test for the quantitative determination of glucose concentration in human serum and plasma on the cobas c111 system. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia.

ISE Chloride Electrode
The chloride electrode for the cobas c111 system is intended for the quantitative determination of chloride in diluted serum, plasma, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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

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

Carol C. Benson

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K071211

Indications for Use

510(k) Number (if known): K071211

Device Name: **cobas c** 111 analyzer and reagents

Indications For Use:

ISE Potassium Electrode
The potassium electrode for the cobas c111 system is intended for the quantitative determination of potassium in diluted serum, plasma, and urine. Measurements of potassium are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

ISE Sodium Electrode
The sodium electrode for the cobas c111 system is intended for the quantitative determination of sodium in diluted serum, plasma, and urine. Measurements of sodium are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

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)

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