MAR 13 2006

K 060373

510(k) Summary: Device Modification— Roche cobas 6000 Series System

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
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Kerwin Kaufman

Date prepared: January 23, 2006

Device Name

Proprietary name: **cobas** 6000 Series system

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

Classification names: Discrete photometric chemistry analyzer for clinical use

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Device Description

The cobas 6000 Series system:

- is fully automated,
- is modular,
- is computerized,
- uses serum/plasma, urine, CSF, and supernatant sample types,
- performs in vitro quantitative and qualitative tests on a wide range of analytes, and
- performs photometric assays and ion-selective electrode measurements on a c 501 module as well as electrochemi-luminescence (ECL) assays on an e 601 module.

The cobas 6000 system comprises the following hardware units, which can be combined in various combinations:

- Control unit
- Core unit cu 150
- c 501 module
- c 601 module

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device Description (continued)

The control unit uses a graphical user interface to control all instrument functions, and is comprised of a printer, TFT monitor, keyboard and mouse and a personal computer using the Windows XP operating system.

The core unit is comprised of several components that manage conveyance of samples to each assigned analytical module. The actual composition of the core unit depends on the configuration of the analytical modules. The core unit comprises at least the sampling unit and one rack rotor as main components. Conveyor line(s) and a second rack rotor are possible extensions. Several other core unit components include the sample rack loader/unloader, a STAT port, a barcode reader (for racks and samples), a water supply and a system interface port.

The c 501 module comprises a photometric unit and an ISE unit (for ion-selective electrode determinations). The photometric unit assays up to 600 in vitro tests per hour on a wide range of analytes. The main components of the c 501 module are a sampling system, a reagent system and a reaction disk system. The c 501 module also contains an integrated ISE unit, providing a potentiometric method for assaying sodium, potassium and chloride samples, processing up to 200 samples (600 tests) per hour.

The e 601 module is *analytically identical* to the Elecsys E170 MODULAR ANALYTICS immunoassay analyzer, which was cleared in a letter to file K961481 / A003. Hardware changes are only cosmetic (shape, color) or housing related (sample rack interface), and do not impact analytical properties or performance of the analyzer. The e 601 module is a muti-test immunoassay system with random access and with a capacity of up to 170 tests per hour. The main components of the e 601 module are a reagent area, a measurement area, a consumables area and a PreClean area.

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Intended use / Indications for use

The **cobas** 6000 series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitiative in vitro determinations using a wide variety of tests. It is optimized for high throughput workloads in the professional environment using a combination of ion selective electrodes (ISE), a photometric analysis unit and an immunoassay analysis module.

The **cobas** c501 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.

The **cobas** e601 analyzer is a fully automated discrete immunoassay analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids.

Predicate Device

We claim substantial equivalence to the predicate devices, the Roche/Hitachi MODULAR ANALYTICS System with MODULAR P and ISE Module, cleared in K953239 / A005, and the Roche Elecsys MODULAR E170, cleared in K961481 / A003.

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device modification, cobas 6000 Series

The table below compares the modified device, **cobas** 6000 Series System to the current device, Roche/Hitachi MODULAR ANALYTICS System.

Topic	Roche/Hitachi MODULAR ANALYTICS System with MODULAR P and ISE Module (K953239 / A005) and MODULAR E170 (K961481 / A003)	cobas 6000 Series System with cobas c 501 and e 601 Analyzers (Modified Device)
System Description		
Intended Use	The MODULAR ANALYTICS for the Serum Work Area is a fully automated system for immunological, potentiometric and photometric analysis. The Hitachi MODULAR P is a fully automated, discrete clinical chemistry analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids. The Roche Elecsys E170 is a fully automated, discrete immunoassay analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids	The **cobas** 6000 series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitiative in vitro determinations using a wide variety of tests. It is optimized for high throughput workloads in the professional environment using a combination of ion selective electrodes (ISE), a photometric analysis unit and an immunoassay analysis module. The **cobas** c501 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device modification, cobas 6000 Series **(continued)**

Topic	Roche/Hitachi MODULAR ANALYTICS System with MODULAR P and ISE Module (K953239 / A005) and MODULAR E170 (K961481 / A003)	cobas 6000 Series System with cobas c 501 and e 601 Analyzers (Modified Device)
System Description (*continued*)		
Intended Use (continued)		The **cobas** e601 analyzer is a fully automated discrete immunoassay analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids.
Measurement principle	• ISE Potentiometry (electrolytes) • Absorbance Photometry (enzymes, substrates, proteins, DAT, TDM) • Electrochemiluminescence Immunoassay method	Same
Reaction modes	Endpoint, kinetic, potentiometric, electro-chemiluminescence	Same
Software SIMILARITIES		
Software	MODULAR ANALYTICS System Software	**cobas** 6000 series System Software (modified MODULAR ANALYTICS software)
Configuration	Several analytical units with one PC and one core	Same

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device modification, cobas 6000 Series (continued)

Topic	Roche/Hitachi MODULAR ANALYTICS System with MODULAR P and ISE Module (K953239 / A005) and MODULAR E170 (K961481 / A003)	cobas 6000 Series System with cobas c 501 and e 601 Analyzers (Modified Device)
Software SIMILARITIES *(continued)*		
Functions performed	Data input, sample processing, result calculation, result reporting, quality control	Same
PC (Controller Unit) functions	Data input (keyboard, disc), data output (screen, printer)	Same
Core Unit functions	Real time database, data input and output (via HOST communication), control of sample conveyer	Same
Analytical Unit(s) functions	Control of analytic processes (pipetting, incubation, detection) Primary Signal processing	Same
Data storage	Real time database in Core unit (storage of System and Application parameters, Calibration Data ,QC Data, Sample results, Alarm history)	Same
Result calculation	Automated measuring of signal for kinetic and endpoint methods according to cycle time and automated calculation of concentrations via calibration curve	Same
User management	Yes	Yes
Flagging of errors	Available	Available

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device modification, cobas 6000 Series (continued)

Topic	Roche/Hitachi MODULAR ANALYTICS System with MODULAR P and ISE Module (K953239 / A005) and MODULAR E170 (K961481 / A003)	cobas 6000 Series System with cobas c 501 and e 601 Analyzers (Modified Device)
Software DIFFERENCES		
Units controlled	MODULAR P analyzer, ISE analyzer, MODULAR D analyzer, E170 analyzer	**cobas** c501 and **cobas** e601 analyzers
HbA1c measurement on **cobas** c501	Hemolysate application as separate assays	Hemolysate application as one assay
Initial cassette volume check (ICVC) for reagent pipetting on **cobas** c501	Not available	Available
Clot detection	Not available on MODULAR P but available on E170	Available on both **cobas** c501 and e601 analyzers
Sample carry over evasion from **cobas** c501 module to the e601 module	One feature implemented to prevent sample carry over from MODULAR P to E170	Additional feature implemented to prevent sample carry over
Data concept (Application parameter, calibrator, control value transfer) for **cobas** c501 and e601 modules	No electronic transfer	Electronic transfer possible (user must accept transfer before parameters applied)
QC concept for **cobas** c501 and e601 modules	Auto QC not available	Auto QC implemented

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

Device Modification, cobas c 501

The table below compares the similarities and differences of the **cobas** c 501 analyzer to the Hitachi MODULAR P analyzer.

Topic	Hitachi MODULAR P (K953239 / A005)	cobas c 501 Analyzer (Modified Device)
Analyzer Features		
Throughput	Max. 800 tests per hour without ISE	Max. 600 tests per hour without ISE
Analyzer size	Stand alone module or multiple modules linked to form one unit	Same
Sample Handling		
Typical sample volumes	2-35 µL	1.0 - 35 µL
Sample types	Serum, plasma, urine, CSF and other depending on the chemistry test	Same
Sample handling system	Input of samples via core input buffer using universal sample racks	Same
Sample capacity on board	300	150
Sample identification	Barcode	Same
Reagent Handling		
Reagent volume	20-270 µL	5-180 µL
Reagent container (electrolytes)	Plastic bottles closed via screwcaps	Same
Reagent container (non-electrolytes)	Plastic bottles closed via screwcaps	Plastic bottles closed via pierceable screwcaps with modified bottle material
Reagent access	Manual opening of reagent bottle prior to placement onboard	Reagent cassette caps pierced onboard by the instrument
Onboard storage temperature	Refrigerated 5-12 °C	Same

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

cobas c 501 (continued)

Topic	Hitachi MODULAR P (K953239 / A005)	cobas c 501 Analyzer (Modified Device)
Reagent Bottle / Cassette identification	Barcode	Same
On board reagent storage capacity	44 rotor channels on 2 rotors to run 44 reagent kits in parallel	60 rotor channels on 1 rotor to run 60 reagent kits in parallel
System cycle time	18 sec	8 sec
Reagent mixing	Stirring	Ultrasonic
Auto rerun	Available	Same
Pipetting System		
Sample and reagent Syringes	XY robotic	Same
Reagent probes	2 polished steel probes	2 polished steel probes with modified design
Sample probes	1 polished steel probe	1 polished steel probe with modified design
Probe cleaning	Automatic for all probes	Same
Liquid level detection	Electrostatic for sample and reagents	Electrostatic for sample Initial Cassette Volume Check (ICVC) and bubble detection for reagent
Clot detection	Not available	Provided
Test Reaction Chamber		
Temperature control	Circulating water bath at 37°C.	Same
Cuvettes	Multiple use	Same

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

cobas c 501 (continued)

Topic	Hitachi MODULAR P (K953239 / A005)	cobas c 501 Analyzer (Modified Device)
ISE Module		
ISE module	Separate ISE Module (K953239 / A005) integrated into MODULAR ANALYTICS System	Module integrated into **cobas** c 501 analyzer; new hardware design with modified pipetting scheme for sample and reagent
Ion selective electrodes (ISEs)	Potentiometric chloride, potassium, sodium and reference electrodes	Same
ISE throughput	Up to 900 tests/hour	Up to 600 tests/hour
Detection Information		
Spectrophotometer	Gradient photometer with discrete photodiodes in fixed array	Same
Light source	Tungsten/halogen	Same
Light path	0.50 cm	0.56 cm
Measuring unit	1	Same
Wavelengths	340, 376, 415, 450, 480, 505, 546, 570, 600, 660, 700, 800 nm	Same
Calibration and quality control		
Calibrators	Multiple use	Same
Calibration modes	Linear, nonlinear	Same
Calibration / on board stability	Typically each lot or 4 weeks for same reagent on board	Typically each lot or 12 weeks for same reagent on board
Control storage on instrument	No	In analyzer remote buffer area at ambient temperature
Calibrator / control value transfer	Via Barcode Transfer Sheet, application disk or manual entry	Via remote transfer or CD-ROM
Internal quality management system	Available to monitor and validate test results	Same

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cobas c 501 (continued)

Interfaces		
Host Interface	RS232C bi-directional	Same
Printer	Dot matrix	Laser
Display	Keyboard + touch-screen	Same Optional use of mouse

Device Modification, cobas e 601

The table below compares the **cobas** e 601 analyzer to the Elecsys MODULAR E170 analyzer.

Topic	Elecsys MODULAR E170 (K961481 / A003)	cobas e 601 Analyzer (Modified Device)
Analyzer Features		
Intended Use	Intended to be used for the in vitro quantitative and qualitative analysis of analytes in body fluids	The **cobas** e601 analyzer is a fully automated discrete immunoassay analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids.
Indication for use	For professional use only	Same
Operating principle	Electrochemiluminescence Immunoassay method	Same
Workflow principle	Random access or batch	Same
Analyzer size	Floor analyzer	Same
Maximum Throughput	170 tests/hour per module	Same

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

cobas e 601 (continued)

Topic	Elecsys MODULAR E170 (K961481 / A003)	cobas e 601 Analyzer (Modified Device)
Configuration	1 stand alone module or 2-4 modules linked together in Roche MODULAR Analytics System	1 stand alone module or up to 2 modules linked together in the **cobas** 6000 Series System
Sample		
Sample material	Serum and Plasma	Same
Sample input	Via sample racks	Same
Positive Identification	Yes	Same
Reagents		
Reagent Kits	Assay RackPack	Same
No. of Channels	25	Same
On-board Temperature	18-22°C	Same
System reagents	ProCell, CleanCell, SysClean, PreClean,* ProbeWash* * *used for specific assays*	Same
Sample Pipetting		
Liquid level detection	Electrostatic sensing	Same
Clot detection	Yes	Same
Pipetting device	Disposable tip	Same
Reagent Pipetting		
Pipetting device	Steel probe	Same
Incubation		
Temperature	37°C	Same
Timing	18 minutes * * specific assays: 17 minutes	Same
Detection		
Device	ECL unit (sipper, cell, PMT)	Same
Channels	2	Same

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510(k) Summary: Device Modification— Roche cobas 6000 Series System, Continued

cobas e 601 (continued)

Topic	Elecsys MODULAR E170 (K961481 / A003)	cobas e 601 Analyzer (Modified Device)
Calibration / Quality Control		
Calibration mode	2-point calibration	Same
Calibrators and Controls	CalSets, CalChecks and Controls	Same
Calibration intervals with each new lot	Mandatory	Same
Calibration stability	4 weeks	Same
Dilution		
On-board	Optional	Same
Disposables		
	Tips	Same
	Assay cups	Same
Failsafe		
Failsafe Concept	Internal Quality Management System on multiple levels: -Control and verification of instrument operation -Data input control -Validation of results -Corresponding Alarm and Flag System	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 13 2006

Kerwin Kaufman, MBA, MT(ASCP)
Regulatory Affairs Principal
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k060373
Trade/Device Name: cobas 6000 Series System
Regulation Number: 21 CFR§862.1600
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Code: CEM, CGZ, CZW, DJG, JFJ, JGS, KNK, LDP, JJE
Dated: February 10, 2006
Received: February 13, 2006

Dear Mr. Kaufman;

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): K060373

Device Name: **cobas 6000 Series System**

Indications For Use:

The **cobas** 6000 series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitiative in vitro determinations using a wide variety of tests. It is optimized for high throughput workloads in the professional environment using a combination of ion selective electrodes (ISE), a photometric analysis unit and an immunoassay analysis module.

The **cobas** c501 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.

The **cobas** e601 analyzer is a fully automated discrete immunoassay analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids.

The α-Amylase EPS ver.2 assay is an in vitro test for the quantitative determination of α-Amylase in serum, plasma and urine on Roche/Hitachi **cobas c** systems. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis.

The Uric Acid ver.2 assay is an in vitro test for the quantitative determination of uric acid in human serum, plasma and urine on Roche/Hitachi **cobas c** systems. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use **XXX** 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)

Office of In Vitro Diagnostic Device Evaluation and Safety

K060373

Indications for Use

510(k) Number (if known): K060373

Device Name: **cobas 6000 Series System**

Indications For Use: (CONTINUED)

The Tina-quant Complement C3c ver.2 assay is an in vitro test for the quantitative determination of Complement C3c in human serum and plasma on Roche/Hitachi **cobas c** systems. Measurement of complement C3c aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

The ISE module of the Roche/Hitachi **cobas c** systems is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

The Acetaminophen assay is an in vitro test for the quantitative determination of toxic levels of acetaminophen in serum and plasma on Roche/Hitachi **cobas c** systems. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

The Opiates II assay is an in vitro diagnostic test for the qualitative and semiquantitative detection of morphine and its metabolites in human urine on Roche/Hitachi **cobas c** systems at cutoff concentrations of 300 and 2000 ng/mL. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Opiates II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose.

Prescription Use **XXX** 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

K060373