K100853

510(k) Summary: Roche cobas 8000 Modular Analyzer Series

Introduction

The information in this 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter name, address, contact

Roche Diagnostics
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SEP 09 2010

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Date prepared: August 19, 2010

Device Name

Proprietary name: **cobas** 8000 Modular Analyzer Series
Common names: Analyzer, Chemistry (Photometric,Discrete), for clinical use
Classification names: Discrete photometric chemistry analyzer for clinical use (21 CFR 862.2160). Product code JJE

Proprietary name: ISE Indirect Na, K, Cl for Gen.2
Regulation Number: 21 CFR 862.1665, Sodium test system
Product Code: JGS
Regulation Number: 21CFR 862.1600, Potassium test system
Product Code: CEM
Regulation Number: 21CFR 862.1170 Chloride test system
Product Code: CGZ

Proprietary name: Tina-quant IgA Gen.2
Regulation Number: 21 CFR 866.5510, IgA, Antigen
Product Code: CZP

Predicate Device

We claim substantial equivalence to the Roche cobas 6000 Analyzer Series predicate device cleared in K060373.

Device Description

The **cobas** 8000 Modular Analyzer Series is a fully automated system for clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids. It is optimized for high throughput workloads in the professional environment using a combination of ion selective electrodes (cobas 8000 ISE module) and photometric analysis modules (cobas c 701 and c 502 modules). The cobas c 701 and c 502 analyzer modules are new members of the Roche / Hitachi family of clinical chemistry analyzers.

The cobas 8000 ISE module is an Ion-selective electrode system for the determination of sodium, potassium and chloride in serum and plasma.

The cobas **c** 701 module is a fully automated, discreet, computerized instrument for in vitro tests on a wide range of analytes. It is designed to use serum/plasma, urine, CSF supernatant and whole blood sample types. The related sample buffer module offers a random access buffer function for samples.

The cobas c 502 module is analytically identical to the cobas c 501 module (cobas 6000 analyzer series, K060373), but without an integrated ISE module. The related sample buffer module offers a random access buffer function for samples.

The cobas 8000 Data Manager acts as a command/control center between the cobas 8000 instrument and the LIS. The data manager software is installed on a PC. It also provides enhanced sample tracking, test management, result traceability, storage and reporting, quality control and calibration management, has LIS backup functionality and serves as a robust storage location for the instrument.

The control unit uses a graphical user interface to control all instrument functions, and is comprised of a touch screen monitor, keyboard and mouse and a personal computer.

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. Features of the Core Unit include a barcode reader (for racks and samples), automatic tube position if barcode position is misaligned, system power switch and circuit breaker, the sample rack loader/unloader, a STAT port, a water supply and a system interface port.

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510(k) Summary: Roche cobas 8000 Modular Analyzer Series, Continued

Intended use / Indications for use

The **cobas** 8000 Modular Analyzer Series is a fully automated system for clinical chemistry analysis, intended for the in vitro qualitative and quantitative determination of analytes in body fluids. It is optimized for high throughput workloads in the professional environment using a combination of ion selective electrodes (ISE) and a photometric analysis unit. This device is intended for use in conjunction with certain materials to measure a variety of analytes that may be adaptable to the below analyzers depending on the reagents used.

The **cobas** c701 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.

The **cobas** c502 analyzer is a fully automated discrete clinical chemistry analyzer intended for the in vitro quantitative / qualitative determination of analytes in body fluids.

The cobas 8000 ISE module is a fully automated ion- specific analyzer intended for the in vitro potentiometric determination of chloride, potassium and sodium in serum and plasma using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

IGA-2 is an in vitro test for the quantitative determination of IgA in human serum and plasma on Roche/Hitachi **cobas c** systems. IgA measurements aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Device modifications

The tables below compare the modified device (cobas c 701, cobas c502 and cobas 8000 ISE analyzers with cobas 8000 system software) to the current device (cobas c 501 with cobas 6000 system software)

Table 1

Topic	cobas c501 analyzer module with ISE and cobas 6000 system software (current device)	cobas c701 and cobas 8000 ISE analyzer modules and cobas 8000 system software (modified device)
Basic features		
Intended Use	Fully automated clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.	Same
Measurement principle	• Absorbance Photometry (enzymes, substrates, proteins, DAT, TDM) • ISE Potentiometry (electrolytes)	Same
Throughput, Photometry	Max. 600 tests per hour without ISE	Max. 2000 tests per hour without ISE
Throughput, ISE Potentiometry	Max. 600 tests per hour	Max. 1800 tests per hour
Reagent Handling		
Reagent container (non-electrolytes)	Plastic bottles closed via pierceable screwcaps	Plastic bottles closed via screwcaps with modified cassette design and modified bottle material
Reagent access	Cassette caps pierced onboard by the instrument	Cassette caps to be opened before placing on instrument
Reagent bottle/Cassette identification	Barcode	RFID
Pipetting System		
Liquid level detection reagent	Initial Cassette Volume Check (ICVC)	Electrostatic
Electrolytes	Reagent transfer steps by pipetting using transfer arms	Reagent transfer steps partly by aspiration using tubes
Software		
Software	cobas 6000 system software	cobas 8000 system software
Core Unit functions	Real time database, data input and output (via HOST communication), control of sample conveyer	Real time database, data input and output (via Data Manager communication), control of sample conveyer
Data storage	Real time database in Core unit (storage of System and Application parameters, Calibration Data ,QC Data, Sample results, Alarm history)	Real time database in Core unit and Data Manager (storage of System and Application parameters, Calibration Data ,QC Data, Sample results, Alarm history)

Table 2

Topic	cobas c501 with ISE and cobas 6000 system software (current device)	cobas c502 analyzer module and cobas 8000 system software (modified device)
Basic features		
Intended Use	Fully automated clinical chemistry analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.	Same
Measurement principle	• Absorbance Photometry (enzymes, substrates, proteins, DAT, TDM) • ISE Potentiometry (electrolytes)	• Same • No ISE module
Software		
Software	cobas 6000 system software	cobas 8000 system software
Core Unit functions	Real time database, data input and output (via HOST communication), control of sample conveyer	Real time database, data input and output (via Data Manager communication), control of sample conveyer
Data storage	Real time database in Core unit (storage of System and Application parameters, Calibration Data ,QC Data, Sample results, Alarm history)	Real time database in Core unit and Data Manager (storage of System and Application parameters, Calibration Data ,QC Data, Sample results, Alarm history)

Reagent Applications: Risk analysis for application of reagents to the cobas 8000 system was conducted by Roche Diagnostics according to internal SOPs.

Based on the risk analysis, application testing done on the cobas c701 and c502, using IgA as a representative assay, included with-in run and between-day precision, linearity, recovery of controls and method comparison to the c501. Sodium, Potassium and Chloride were also tested on the ISE module. Testing included with-in run and between-day precision, linearity, recovery of controls and method comparison to the c501 as well as to flame for sodium and potassium and coulometry for chloride. All testing met specifications.

Conclusion: The cobas 8000 Modular Analyzer Series is substantially equivalent to the predicate cobas 6000 analyzer series in design, modes of operation, assay performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Roche Diagnostics
c/o Mr. Angelo Pereira
Regulatory Affairs Principle
9115 Hague Rd
Indianapolis IN 46250

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Re: k100853
Trade/Device Name: cobas 8000 Modular Analyzer Series
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: CEM, JGS, CGZ, CZP, JJE
Dated: August 20, 2010
Received: August 23, 2010

SEP 09 2010

Dear Mr. Pereira:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Indications for Use

K100853
SEP 09 2010

510(k) Number (if known): **K100853**

Device Name: **cobas 8000 Modular Analyzer Series**

Indications For Use:

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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)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100853