K123726

510(k) Summary: cobas 8000 ISE Module, Urine Sample Type

MAY 2 1 2013

Introduction

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

Submitter name, address, and contact

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9115 Hague Road
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Date Prepared: November 30, 2012

Device name

Proprietary name:	cobas 8000 ISE Indirect Na, K, Cl for Gen. 2.
Common name:	Sodium Test System Potassium Test System Chloride Test System
Classification:	Ion-Specific Electrode Sodium Ion-Specific Electrode Potassium Ion-Specific Electrode Chloride

Establishment registration

For the cobas 8000 ISE module, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics, United States is 1823260.

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Classification

The FDA has classified the Sodium, Potassium, and Chloride Test Systems as Class II devices.

Panel	Product Code	Classification Name	Regulation
Clinical Chemistry (75)	JGS	Ion Specific Electrode, Sodium	21 CFR 862.1665
Clinical Chemistry (75)	CEM	Ion Specific Electrode, Potassium	21 CFR 862.1600
Clinical Chemistry (75)	CGZ	Ion Specific Electrode, Chloride	21 CFR 862.1170

Proposed labeling

Draft labeling sufficient to describe the device, its intended use, and the directions for use on the **cobas 8000 Urine ISE** analyzer module is included in the submission.

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Device description

The cobas 8000 ISE module is an Ion-Selective Electrode (ISE) system for the determination of sodium, potassium, and chloride in serum, plasma, and urine. The cobas 8000 ISE module and the ISE Gen 2 reagents were previously cleared for serum and plasma sample types under K100853. This premarket notification seeks to obtain FDA review and clearance for the urine sample type for the ISE Gen 2 reagents on the cobas 8000 ISE module.

An ISE makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions will closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The EMF develops according to the Nernst equation for a specific ion in solution (see package insert for further explanation). Please refer to K100853 for detailed hardware and software information relating to the cobas 8000 modular analyzer series.

Commercially available controls are recommended for the urine sample type. Aqueous ISE standard calibrators (S1, S2, and S3) were cleared under K053165 and ISE Compensator under K052193.

Intended use

The ISE module of the Roche/Hitachi **cobas c** system is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes.

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510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Indications for use

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, plasma, and urine using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

Substantial equivalence - comparison

The following table compares the cobas 8000 ISE module and its predicate device the COBAS INTEGRA ISE cleared under K963627.

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510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Comparison of Systems – similarities and differences

System Comparison		
Parameter	**Predicate COBAS INTEGRA ISE K963627**	**cobas 8000 ISE Module, Urine Sample Type**
Intended use	The COBAS INTEGRA ISE module applications are intended for use for the quantitative determination of sodium, potassium, chloride, and lithium in serum, plasma or urine using ion-selective electrodes.	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.
Specimen Type	Serum, Plasma, Urine	Same (this submission only applies to the urine sample type)
Measurement principle	ISE Potentiometry	Same
Reagent container	Plastic bottles closed via screw caps	Same
Onboard storage temperature	Room Temperature	Same
ISE Module	Integrated into Integra analyzer	Separate ISE module connected to Core cobas 8000 module
Ion Selective electrodes (ISEs)	Potentiometric chloride, potassium, sodium and reference electrodes	Same
Sample Dilution	1:6	1:46
Throughput	Max 600 tests/hour	Max 1800 tests/hour

510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Comparison of assays – similarities and differences (Sodium)

Assay Comparison Sodium						
Parameter	**Predicate Cobas Integra ISE (K963627)**			**cobas 8000 Urine ISE**		
Repeatability		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	56	1.0	Low	66.4	0.4	0.6
	High	259	0.49	Med	178.9	0.9	0.5
				High	321.7	0.7	0.2
				Liq 1	81.1	0.3	0.4
				Liq 2	170.6	0.5	0.3
Intermediate precision (CLSI)		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	56	3.0	Low	68.6	1.1	1.6
	High	259	1.2	Med	180.3	1.0	0.6
				High	318.0	2.1	0.7
				Liq 1	82.7	1.2	1.4
				Liq 2	171.3	1.0	0.6
Method Comparison to reference (flame photometer)	Not provided in labeling			N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.976 Intercept (Bablok) = 4.3548 Range (X) = 65.7 - 327.7		
Method comparison to predicate	N = 174 Correlation = 0.996 Slope = 0.95 Intercept = 3.4			N = 59 Days = 2 Correlation = 0.9996 Slope (Bablok) = 0.930 Intercept (Bablok) = 12.0671 Range (X) = 63.8 - 339.2		
Detection Limits	Not determined			LOB = 7.55 mmol/L LOD = 8.88 mmol/L LOQ = 49.53 mmol/L		
Reportable range	20-350 mmol/L			60-350 mmol/L		
Extended Range	No Extended Range			No Extended Range		

510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Comparison of assays – similarities and differences, (Potassium)

Assay Comparison Potassium						
Parameter	**Predicate** **Cobas Integra ISE (K963627)**			**cobas 8000 Urine ISE**		
Repeatability		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	33	0.26	Low	3.65	0.00	1.2
	High	125	2.0	Med	51.10	0.30	0.6
				High	83.78	0.66	0.8
				Liq 1	32.19	019	0.6
				Liq 2	69.47	0.39	0.6
Intermediate precision (CLSI)		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	33	1.4	Low	3.75	0.06	1.7
	High	125	2.0	Med	49.48	0.65	1.3
				High	80.60	1.32	1.6
				Liq 1	31.32	0.37	1.2
				Liq 2	67.49	1.17	1.7
Method Comparison to reference (flame photometry)	Not provided in labeling			N = 59 Days = 2 Correlation = 0.9993 Slope (Bablok) = 0.962 Intercept (Bablok) = 1.7605 Range (X) = 4.20 - 91.90		
Method comparison to predicate	N = 162 Correlation = 0.999 Slope = 1.04 Intercept = -0.7			N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.920 Intercept (Bablok) = 1.4589 Range (X) = 3.98 - 97.74		
Detection Limits	Not determined			LOB = 0.32 mmol/L LOD = 0.35 mmol/L LOQ = 2.33 mmol/L		
Reportable range	1-150 mmol/L			3-100 mmol/L		
Extended Range	No Extended Range			No Extended Range		

510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Comparison of assays – similarities and differences, (Chloride)

Assay Comparison Chloride						
Parameter	**Predicate Cobas Integra ISE (K963627)**			**cobas 8000 Urine ISE**		
Repeatability		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	147	0.44	Low	63.6	0.5	0.7
	High	274	0.30	Med	180.8	0.9	0.5
				High	341.7	1.1	0.3
				Liq 1	92.3	0.4	0.5
				Liq 2	189.6	0.6	0.3
Intermediate precision (CLSI)		Mean [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	147	1.1	Low	64.7	1.1	1.7
	High	274	2.1	Med	179.7	1.2	0.7
				High	336.5	3.5	1.0
				Liq 1	92.6	1.1	1.2
				Liq 2	187.6	1.6	0.9
Method Comparison to reference (coulometry)	N = 164 Correlation = 0.981 Slope = 0.95 Intercept = 11.0			N = 59 Days = 2 Correlation = 0.9985 Slope (Bablok) = 1.092 Intercept (Bablok) = -11.2893 Range (X) = 66.0 - 324.0		
Method comparison to predicate	Not provided in labeling			N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.952 Intercept (Bablok) = 0.5078 Range (X) = 65.2 - 350.0		
Detection Limits	Not determined			LOB = 8.70 mmol/L LOD = 9.66 mmol/L LOQ = 48.03 mmol/L		
Reportable range	20-350 mmol/L			60-350 mmol/L		
Extended Range	No Extended Range			No Extended Range		

510(k) Summary: cobas 8000 ISE Module, Urine Sample Type, *Continued*

Evaluations summary	The cobas 8000 ISE Module, Urine Sample Type was evaluated for several performance characteristics, including repeatability, intermediate precision, LoB, LoD, LoQ, method comparison, recovery in controls, and linearity.
Conclusion	The ISE Gen 2 reagents applied to the cobas 8000 ISE analyzer is substantially equivalent to the predicate COBAS INTEGRA ISE cleared under K963627.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

Roche Diagnostics
C/O David Tribbett
9115 Hague Road
INDIANAPOLIS IN 46250

Re: K123726
Trade/Device Name: cobas 8000 ISE Indirect Na, K, Cl for Gen. 2.
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: II
Product Code: JGS, CEM, CGZ
Dated: April 4, 2013
Received: April 9, 2013

Dear Mr. Tribbett:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123726

Device Name: cobas 8000 ISE Indirect Na, K, Cl for Gen. 2

Indications for Use:

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, plasma, and urine using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123726