K063684

510(k) Summary – cobas c501 Lithium

MAR 21 2008

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

Contact person: Theresa Ambrose Bush

Date prepared: January 14, 2008

Device Name

Proprietary name: Lithium

Common name: LI

Classification name: Lithium

Device Description

The cassette cobas c501 Lithium contains an in vitro diagnostic reagent system intended for use on Roche/Hitachi cobas c systems for the quantitative determination of lithium in human serum and plasma.

The test principle is colorimetric.

Intended use

In vitro test for the quantitative determination of lithium in human serum and plasma on Roche/Hitachi cobas c systems.

Predicate Device

We claim substantial equivalence to the COBAS INTEGRA ISE Direct cleared as K963627

Substantial equivalency – Similarities

The table below indicates the similarities between the modified Lithium test and its predicate device (COBAS INTEGRA ISE Direct, K963627).

Feature	Predicate device: ISE Direct (K963627)	Modified device: Lithium
General		
Intended Use/ Indications for Use	The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride and lithium concentrations in undiluted serum and plasma using ion-selective electrodes.	In vitro test for the quantitative determination of lithium in human serum and plasma on Roche/Hitachi cobas c systems.
Specimen type	Serum and plasma	Same
Test principle		
Reference method	Ion-selective electrodes using undiluted specimens (ISE Direct)	Colorimetric test
Reagent information		
Stability - shelf life and on-board	1 day at 15 to 25° C 7 days at 4° C stable at -20 ° C	1 day at 15 to 25° C 7 days at 2-8° C 6 months at (-15) to (-25) ° C
Calibrator	ISE Solutions 1, 2 and 3 ISE Calibrator Direct 5 hrs (main calibration) Every sample (one-point calibration)	C.f.a.s. After 24 hrs, reagent pack change, reagent lot change
Quality control	Precinorm U and Precipath U	Precinorm U and Precipath U Precinorm U plus and Precipath U
Traceability	Gravimetrically traceable to high purity inorganic reference material	Atomic Absorption Spectroscopy
Performance characteristics		
Expected values (literature reference)	Therapeutic concentration: 0.6-1.2 mmol/L Toxic concentration:>2.0 mmol/L	Same
Method comparison		
Method comparison	Passing Bablok: $y = 1.037x + 0.004$ $\tau = 0.940$ Linear regression: $y = 1.044x - 0.000$ $r = 0.995$	

Substantial equivalency – Differences

The table below indicates the differences between the modified Lithium test and its predicate device (COBAS INTEGRA ISE Direct, K963627).

Feature	Predicate device: ISE Direct (K963627)	Modified device: Lithium
Test principle		
Reference method	Ion-selective electrodes using undiluted specimens (ISE Direct)	Colorimetric test
Performance characteristics		
Precision	Within run CV: 2.5% @ 4.4 mmol/L 0.81% @ 1.9 mmol/L Total: 3.4% @ 0.443 mmol/L 2.5% @ 33.2 mmol/L	Within run CV: 1.7% @ 0.77 mmol/L 1.0% @ 2.38 mmol/L 1.9% @ 0.46 mmol/L 1.2% @ 1.40 mmol/L Total: 2.2% @ 0.79 mmol/L 1.3% @ 2.42 mmol/L 2.3% @ 0.61 mmol/L 1.6% @ 1.62 mmol/L
Endogenous interferences	Hemolysis: levels higher than 1 g/L increase lithium concentrations significantly Icterus no significant interferences Lipemia: highly lipemic specimens may interfere with ISE fluid detection causing the flag NO FLUID	No significant interference up to: Hemolysis: H index of 1000 Icterus: I index of 37 for conjugated and 43 for unconjugated bilirubin Lipemia: L index of 2000
Exogenous Interferences	Phenylpropamine and pseudoephedrine interfere with the membrane of the lithium electrode.	NH4Cl: 19.8 umol/L NaCl : 140 mmol/L KCl : 4 mmol/ L CaCl2: 2.4 mmol/L MgCl2: 0.9 mmol/L FeCl3: 1.04 mg/L Cu (NO3)2: 1.15 mmol/L ZnCl2: 1.07 mmol (none of these are in the physiological key interference range) In very rare cases gammopathy may cause unreliable results.

Limit of Detection (per CLSI EP17)	Not stated	0.05 mmol/L
Limit of Blank	Not stated	0.03 mmol/L
Measuring range	0.1-4 mmol/L	0.05-3.00 mmol/L Extended measuring range: 0.05-6.00 mmol/L

Performance evaluation

The cobas c501 test system was evaluated for several performance characteristics.

In addition, the traceability, value assignment process, and stability of the lithium analyte within the c.f.a.s. calibrator are described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Dr. Theresa Ambrose Bush
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

MAR 21 2008

Re: k063684
Trade/Device Name: Lithium Test System
Regulation Number: 21 CFR 862.3560
Regulation Name: Lithium test system
Regulatory Class: Class II
Product Code: NDW, JIX
Dated: March 7, 2008
Received: March 14, 2008

Dear Dr. Bush:

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): K063684

Device Name: **Lithium test system**

Indications For Use:

In vitro test for the quantitative determination of lithium in human serum and plasma on Roche/Hitachi cobas c systems. Measurements of lithium are used as an aid in the management of patients taking lithium for the treatment of mental disturbances such as manic-depressive illness (bipolar disorder).

Prescription Use **XXXX** 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

(Optional) K063684