FEB 1 6 2006

K 060108

510(k) Summary - Chloride Electrode Gen. 2

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 Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3831

Contact person: Corina Harper

Date prepared: January 12, 2006

Chloride Electrode Gen. 2

Proprietary name: COBAS INTEGRA Chloride Electrode Gen. 2

Common name: Chloride Test System

Classification name: Ion-Specific Electrode Chloride

Device description

The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride in serum, plasma and urine, and lithium in serum and plasma, using ion-selective electrodes.

The ion-selective electrode is using undiluted (ISE Direct) or automatically diluted (ISE Indirect, ISE Urine) specimens.

This Chloride electrode is recommended to be used if a significant amount of the samples are plasma samples. Serum and urine samples may also be analyzed with this electrode.

Continued on next page

510(k) Summary - Chloride Electrode Gen. 2, Continued

Intended use

The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride in serum, plasma and urine, and lithium in serum and plasma, using ion-selective electrodes.

This Chloride electrode is recommended to be used if a significant amount of the samples are plasma samples. Serum and urine samples may also be analyzed with this electrode.

Predicate Device

We claim substantial equivalence to the currently marketed ISE Chloride Electrode cleared for use under K963627 on October 24, 1996.

Substantial equivalency - similarities

The table below indicates the similarities between the predicate device (K963627) and the modified Chloride Electrode Gen. 2.

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
General		
Intended Use	ISE Direct: 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 electrode. ISE Indirect: The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride concentrations in diluted serum and plasma using ion-selective electrode. ISE in Urine: The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride concentrations in diluted urine using ion-selective electrode.	The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride in serum, plasma and urine, and lithium in serum and plasma, using ion-selective electrodes. This Chloride electrode is recommended to be used if a significant amount of the samples are plasma samples. Serum and urine samples may also be analyzed with this electrode.
Sample type	Serum, plasma, urine	Same

Continued on next page

510(k) Summary - Chloride Electrode Gen. 2, Continued

Substantial equivalency - similarities (continued)

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
Electrode Information		
Calibrator	ISE solutions 1,2,3 ISE Calibrator Direct ISE Calibrator Indirect/Urine 5 hours calibration interval (main calibration), every sample (one-point calibration)	Same
Quality control	Serum/Plasma: PreciNorm U, Precipath U Urine: Quantitative Urine Controls	Same
Performance Characteristics		
Expected values for adults - mmol/L	ISE Direct Serum/Plasma 101-110 ISE Indirect Serum/plasma 98-107 ISE Urine 110-250	Same

Continued on next page

510(k) Summary - Chloride Electrode Gen. 2, Continued

Substantial equivalency - similarities (continued)

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
Endogenous Interferences	ISE Direct and Indirect (serum/plasma): Hemolysis – no significant interferences up to a hemoglobin level of 10 g/L Lipemia - no significant interferences Icterus – no significant interferences	Same
Exogenous Interference	ISE Direct (serum/plasma) Probenecid causes artificially high chloride concentrations. Salicylic acid concentration of 1.2 mmol/L increase chloride concentration by aprox. 10% ISE Indirect (serum/plasma) Acetylsalicylic acid causes artificial high Chloride concentrations. ISE Urine Drug panel tested caused no significant interferences up to the indicated concentrations in the label.	ISE Direct (serum/plasma) Ca-Dobesilate, Phenylbutazone, Acetylsalicylic acid and Ibuprofen causes artificially high chloride concentrations. Same ISE Indirect(serum/plasma) Acetylsalicylic acid and Ibuprofen causes artificial high chloride concentrations. ISE Urine: Ascorbic acid, Ca-Dobesilate and Levodopa causes artificially high chloride concentrations.

Continued on next page

510(k) Summary - Chloride Electrode Gen. 2, Continued

Substantial equivalency - differences

The table below indicates the differences between the predicate device (K963627) and the modified Chloride Electrode Gen. 2.

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
Onboard Stability	3 months (serum samples only, reduced when plasma sample are used)	2 months or 6000 samples (when majority of plasma samples are used)
Performance Characteristics		
Precision ISE Direct mode CV%	Within run CV% (n=20): 0.69% @ 86 mmol/L 0.46% @ 99mmol/L Between run CV% (n=20): 1.3% @ 86 mmol/L 0.92%@ 99 mmol/L	Within run CV% (n=21): Serum: 0.19% @ 92.9 mmol/L 0.19% @ 127.2 mmol/L Plasma (low n=20, high n=21): 0.36% @ 89.2 mmol/L 0.15% @ 125 mmol/L Between day CV% (n=21): Serum: 0.9% @ 94.3 mmol/L 1.1% @ 126.5 mmol/L Plasma: 1.0% @ 91.6 mmol/L 1.2% @ 126.0 mmol/L Total CV% Serum: 0.9%@ 94.4 mmol/L 1.1% @ 126.4 mmol/L Plasma: 1.0% @ 91.8 mmol/L 1.4% @ 125.8 mmol/L

Continued on next page

510(k) Summary - Chloride Electrode Gen. 2, Continued

Substantial equivalency - differences (continued)

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
Performance Characteristics		
ISE Indirect mode CV%	Within run CV% (n=20): 0.77% @ 87 mmol/L 0.72% @ 101 mmol/L Between run CV% (n=20): 1.5% @ 87 mmol/L 1.2%@ 101 mmol/L	Within run CV%(n=21): Serum: 0.65% @ 90.3 mmol/L 0.25% @ 124.1 mmol/L Plasma: 0.29% @ 86.4 mmol/L 0.23% @ 121.9 mmol/L Between day CV%(n=21): Serum: 1.0% @ 92.0 mmol/L 0.9% @ 122.8 mmol/L Plasma: 1.1% @ 88.7 mmol/L 1.0% @ 121.6 mmol/L Total CV%: Serum: 1.0%@ 92.1mmol/L 1.0% @ 122.8 mmol/L Plasma: 1.1% @ 88.8 mmol/L 1.0% @ 121.6 mmol/L

510(k) Summary - Chloride Electrode Gen. 2, Continued

Substantial equivalency - differences (continued)

Feature	Predicate Device – Chloride Electrode (approved via K963627)	Modified Chloride Electrode Gen. 2
ISE Urine mode CV%	Within run CV% (n=20): 0.97% @ 53 mmol/L 1.2%@ 267 mmol/L Between run CV% (n=20): 2.8% @ 53 mmol/L 2.2%@ 267 mmol/L	Within run CV% (low n=21, high n=20): 0.5% @ 61.4 mmol/L 0.5% @ 194.4 mmol/L Between day (n=21): 2.3% @ 64.9 mmol/L 4.3% @ 186.4 mmol/L Total: 2.8%@ 65.1mmol/L 4.4% @ 186.5 mmol/L
Linearity (mmol/L)	ISE Direct - Serum/plasma: 20-250 ISE Indirect - Serum/plasma: 20-250 ISE Urine: 20-350	ISE Direct – Serum/Plasma: 60-140 ISE Indirect – Serum/Plasma: 60-140 ISE Urine: 20-250
Sensitivity for electrode: slope	-42 to -56 mV/dec	ISE Direct: -35 to -56 mV/dec ISE Indirect: -38 to -56 mV/dec

Continued on next p

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 16 2006

Ms. Corina Harper
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

Re: k060108
Trade/Device Name: Chloride Electrode Gen. 2
Regulation Number: 21 CFR§ 862.1170
Regulation Name: Chloride test system
Regulatory Class: Class II
Product Code: CGZ
Dated: January 12, 2006
Received: January 27, 2006

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) 276-0484. 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):

Chloride Electrode Gen. 2: **Chloride Electrode Gen. 2**

Indications For Use:

The ISE module of the COBAS INTEGRA systems is intended for use for the quantitative determination of sodium, potassium, chloride in serum, plasma and urine, and lithium in serum and plasma, using ion-selective electrodes.

This Chloride electrode is recommended to be used if a significant amount of the samples are plasma samples. Serum and urine samples may also be analyzed with this electrode.

Chloride measurements are used in diagnosis and treatment of electrolyte and metabolic disorders.

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

...on Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060108