510(k) Summary

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 Road
Indianapolis, IN 46250
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Contact Person: Kay A. Taylor
Date Prepared: July 9, 2007

Device Name

Proprietary name: Elecsys PTH Immunoassay
Elecsys PTH STAT Immunoassay

Common name: Parathyroid Hormone Assay

Classification name: Radioimmunoassay, Parathyroid Hormone

Device Description

The Elecsys PTH and Elecsys PTH STAT Assays are two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

Intended use/Indications for Use

The Elecsys PTH Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma as an aid in the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.

The Elecsys PTH STAT Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.

510(k) Summary, Continued

Substantial equivalence

The Elecsys PTH and Elecsys PTH STAT Test Systems are substantially equivalent to other devices legally marketed in the United States. The Elecsys PTH and Elecsys PTH STAT Immunoassays (expanded intended use) are equivalent to the Elecsys Parathyroid Hormone Test System (K992680).

Device Comparison Table

The following table compares the Elecsys PTH and Elecsys PTH STAT Test Systems and the predicate device. The predicate labeling used as the source document for the comparison is that provided to FDA in K961481/A003.

Comparison Table

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Intended Use/Indications for Use	Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.	The Elecsys PTH Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma as an aid in the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.	The Elecsys PTH STAT Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.
Assay Protocol	Sandwich assay	Same	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same	Same

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Platform(s)	Elecsys 1010, Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411 and **cobas e** 601 analyzers. ***Note**: The **cobas e** analyzers are cleared platforms. Labeling including these analyzers will be manufactured as existing inventories of the product are depleted.*	Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411 and **cobas e** 601 analyzers.	Elecsys 1010, Elecsys 2010 and **cobas e** 411
Total Assay Duration	Elecsys 1010: **9 minute application** Elecsys 2010, cobas e 411 MODULAR ANALYTICS E170, and **cobas e** 601: **18 minute application**	18 minute	9 minute
Sample Type	Human serum and plasma treated with K_3-EDTA.	Same	Same
Calibrator	Elecsys PTH CalSet	Same	Elecsys PTH STAT CalSet
Reagent Stability	**Unopened:** 2-8°C – Up to the stated expiration date **Opened:** 2-8°C – 12 weeks On the E170/**cobas e** 601 and Elecsys 2010/**cobas e** 411: 8 weeks On the Elecsys 1010: 4 weeks (stored alternately in the refrigerator and on the analyzer- ambient temperature 20-25°C; up to 20 hours opened in total.)	**Unopened:** 2-8°C – Up to the stated expiration date **Opened:** 2-8°C – 12 weeks On the E170/**cobas e** 601 and Elecsys 2010/**cobas e** 411: - 8 weeks	**Unopened:** 2-8°C – Up to the stated expiration date **Opened:** 2-8°C – 12 weeks On Elecsys 2010 and **cobas e** 411: 8 weeks On Elecsys 1010: 4 weeks (stored alternately in the refrigerator and on the analyzer- ambient temperature 20-25°C; up to 20 hours opened in total.)
Measuring Range	1.20 – 5,000 pg/mL	Same	Same
Analytical sensitivity (LDL)	1.20 pg/mL (0.127 pmol/L)	Same	Same

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Analytical Specificity	For the monoclonal antibodies used, the following cross-reactivities were found: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–Crosslaps: no cross-reactivity detectable.	Same – reworded to be more clear No cross-reactivities were found for: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–CrossLaps.	Same – reworded to be more clear No cross-reactivities were found for: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–CrossLaps.
Traceability / Standardization	This method has been standardized against a commercially available PTH test (RIA).	Same –slightly wording change. This method has been standardized against a commercial PTH test (RIA).	This method has been standardized against Elecsys PTH. This in turn was standardized against a commercial PTH test (RIA).
Hook Effect	No high dose hook effect at PTH concentrations up to 17,000 pg/mL.	Same	Same
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: E170/**cobas e** 601 and Elecsys 2010/**cobas e** 411: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: E170/**cobas e** 601 and Elecsys 2010/**cobas e** 411: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer).	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: Elecsys 2010/**cobas e** 411: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Precision	Elecsys 1010/ 2010: Within-run Mean 5.4% CV @ 30.0 pg/mL 4.0% CV @ 62.2 pg/mL 4.0% CV @ 271 pg/mL 5.8% CV @ 44.3 pg/mL 3.4% CV @ 161 pg/mL 3.9% CV @ 702 pg/mL Total Mean 5.9% CV @ 30.0 pg/mL 4.3% CV @ 62.2 pg/mL 4.3% CV @ 271 pg/mL 7.1% CV @ 44.3 pg/mL 5.0% CV @ 161 pg/mL 5.4% CV @ 702 pg/mL *E170:* Within-run Mean 2.0% CV @ 25.0 pg/mL 1.2% CV @ 39.8 pg/mL 1.1% CV @ 139 pg/mL 2.2% CV @ 82.2 pg/mL 2.8% CV @ 265 pg/mL 0.6% CV @ 1,215 pg/mL Within-run Mean 3.4% CV @ 26.4 pg/mL 2.5% CV @ 91.5 pg/mL 2.8% CV @ 269 pg/mL 1.7% CV @ 82.7 pg/mL 1.6% CV @ 267 pg/mL 1.6% CV @ 1,222 pg/mL	Elecsys 2010/cobas e411: Within-run Mean 2.7% CV @ 26.7 pg/mL 1.6% CV @ 52.5 pg/mL 1.5% CV @ 261 pg/mL 4.1% CV @ 20.2 pg/mL 2.2% CV @ 58.0 pg/mL 1.9% CV @ 676 pg/mL Total Mean 6.5% CV @ 26.7 pg/mL 3.9% CV @ 52.5 pg/mL 3.0% CV @ 261 pg/mL 6.2% CV @ 20.2 pg/mL 4.1% CV @ 58.0 pg/mL 2.6% CV @ 676 pg/mL *E170/ cobas e601:* Within-run Mean 2.0% CV @ 21.9 pg/mL 1.2% CV @ 35.0 pg/mL 1.1% CV @ 123 pg/mL 2.2% CV @ 72.7 pg/mL 2.8% CV @ 236 pg/mL 0.6% CV @ 1,092 pg/mL Within-run Mean 3.4% CV @ 23.2 pg/mL 2.5% CV @ 80.9 pg/mL 2.8% CV @ 240 pg/mL 1.7% CV @ 73.0 pg/mL 1.6% CV @ 238 pg/mL 1.6% CV @ 1,098 pg/mL	Elecsys 1010: Within-run Mean 5.4% CV @ 30.0 pg/mL 4.0% CV @ 62.2 pg/mL 4.0% CV @ 271 pg/mL 5.8% CV @ 44.3 pg/mL 3.4% CV @ 161 pg/mL 3.9% CV @ 702 pg/mL Total Mean 5.9% CV @ 30.0 pg/mL 4.3% CV @ 62.2 pg/mL 4.3% CV @ 271 pg/mL 7.1% CV @ 44.3 pg/mL 5.0% CV @ 161 pg/mL 5.4% CV @ 702 pg/mL *Elecsys 2010/cobas e411:* Within-run Mean 2.1% CV @ 53.4 pg/mL 1.7% CV @ 215 pg/mL 1.7% CV @ 980 pg/mL 1.6% CV @ 52.6 pg/mL 2.0% CV @ 182 pg/mL 1.8% CV @ 744 pg/mL Within-run Mean 3.8% CV @ 53.4 pg/mL 2.8% CV @ 215 pg/mL 2.5% CV @ 980 pg/mL 1.9% CV @ 52.6 pg/mL 2.5% CV @ 182 pg/mL 2.2% CV @ 744 pg/mL

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Limitations	The assay is unaffected by: Icterus (bilirubin <1,112 µmol/L or <65 mg/dL hemolysis (Hb < 0.932 mmol/L or < 1.5 g/dL), Lipemia (Intralipid < 1,500 mg/dL) Biotin (<205 nmol/L or < 50 ng/mL)	**Do not analyze samples that show visible signs of hemolysis.** The assay is affected by hemolysis > or equal to 0.10 g/dL. For PTH results < 50 pg/mL, hemolysis (Hg< 0.0932 mmol/L or ≥0.10 g/dL) can lead to a reduction oby 3 to 5 pg/mL For PTH results ≥ 50 pg/mL, hemolysis (Hg< 0.0932 mmol/L or ≥0.15 g/dL)affect the results by less than 10 percent. The assay is unaffected by icterus (bilirubin <1,112 µmol/L or <65 mg/dL), lipemia (Intralipid < 1,500 mg/dL), biotin (<205 nmol/L or < 50 ng/mL).	**Do not analyze samples that show visible signs of hemolysis.** The assay is affected by hemolysis > or equal to 0.25 g/dL. The assay is unaffected by icterus (bilirubin <1,112 µmol/L or <65 mg/dL), lipemia (Intralipid < 1,500 mg/dL), biotin (<205 nmol/L or < 50 ng/mL).
	In patients receiving therapy with high biotin doses (i.e > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration	Same	Same
	No interference was observed from rheumatoid factors up to a concentration of 1,500 IU/mL	Same	
	In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found. As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been tested with monoclonal mouse antibodies or have received them for diagnostic purposes.		

Feature	Predicate Device Elecsys PTH Assay (K992680)	Modified Device Elecsys PTH (18 minute appl.)	Modified Device Elecsys PTH STAT (9 minute appl.)
Limitations, continued	In rare cases, interference due to extremely high titers of antibodies to ruthenium can occur. The test contains additives which minimize these effects. Extremely high titers of antibodies to streptavidin can occur in isolated cases and cause interference. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 2007

Roche Diagnostics Corp.
c/o Ms. Kay Taylor
Regulatory Affairs Principal
9115 Hague Road
P.O. Box 50457
Indianaoplis, IN 46250-0457

Re: k070709
Trade/Device Name: Elecsys PTH Immunoassay and Elecsys PTH STAT Immunoassay
Regulation Number: 21 CFR §862.1545
Regulation Name: Parathyroid hormone test system.
Regulatory Class: Class II
Product Code: CEW
Dated: June 18, 2007
Received: June 20, 2007

Dear Ms. Taylor:

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

Indication for Use

510(k) Number (if known): **K070709**

Device Name: Elecsys PTH Immunoassay and Elecsys PTH STAT Immunoassay

Indication For Use:

Elecsys PTH Immunoassay:

The Elecsys PTH: Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. The Elecsys PTH assay can be used intraoperatively.

Elecsys PTH STAT Immunoassay:

The Elecsys PTH STAT: Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. The Elecsys PTH STAT assay can be used intraoperatively.

Prescription Use XXXX (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (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 Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

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

510(k)_ **K070709**