K103162

NOV 18 2010

# 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, P.O. Box 50416
Indianapolis, IN 46250-0416
317-521-3577

Contact Person: Kelly French
Phone: 317-521-3208
Fax: 317-521-2324
Email: kelly.french@roche.com

Secondary Contact: Stephanie Greeman
Phone: 317-521-2458
Fax: 317-521-2324
Email: stephanie.greeman@roche.com

Date Prepared: October 11, 2010

**Device Name**

Proprietary name: Elecsys Parathyroid Hormone CalCheck 5
Common name: PTH CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

**Predicate device**

The Elecsys PTH CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed PTH CalCheck (K993642).

**Device Description**

The Elecsys PTH CalCheck 5 is a lyophilized product consisting of human PTH in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

**Intended use**

The Elecsys PTH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys PTH quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.

*Continued on next page*

**Comparison Table**

The table below compares Elecsys PTH CalCheck 5 with the predicate device, Elecsys PTH CalCheck (K993642). The predicate shows that PTH CalCheck 5 is substantially equivalent to PTH CalCheck, with several key similarities, especially the analyte. The shaded fields indicate similar characteristics between the candidate device and the predicate device.

| **Characteristic** | **Elecsys PTH CalCheck 5 (Candidate Device)** | **Elecsys PTH CalCheck (K993642)** |
|---|---|---|
| Intended Use | The Elecsys PTh Calcheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys PTH quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. For in vitro diagnostic use only. | For use in periodic verification of the calibration of the Elecsys Parathyroid Hormone test. |
| Analyte | PTH | PTH |
| Levels | Five | Three |
| Assay Measuring Range | 1.20 – 5000 pg/mL | 1.20 – 5000 pg/mL |
| Check Target Values | Check 1: ≤ 1 pg/mL<br>Check 2: 60 pg/mL<br>Check 3: 2500 pg/mL<br>Check 4: 4000 pg/mL<br>Check 5: 5000 pg/mL | Check 1: < 5 pg/mL<br>Check 2: 60 pg/mL<br>Check 3: 3000 pg/mL |
| Format | Lyophilized | Lyophilized |
| Handling | Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion. | Reconstitute Check 1, Check 2, and Check 3 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion. |
| Stability | Unopened:<br>• Store at 2-8°C until expiration date<br>Reconstituted:<br>• 20-25°C: 5 hours | Unopened:<br>• Store at 2-8°C until expiration date<br>Reconstituted:<br>• 20-25°C: 4 hours |
| Matrix | Human serum matrix | Human serum matrix |

*Continued on next page*

**510(k) Summary,** Continued

| | |
|---|---|
| **Performance Characteristics** | The Elecsys PTH CalCheck 5 was evaluated for value assignment and stability. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Roche Professional Diagnostics
c/o Ms. Kelly French, Regulatory Affairs Consultant
9115 Hague Road
PO Box 50416
Indianapolis, IN 46250-0416

NOV 18 2010

Re: k103162
Trade/Device Name: Elecsys PTH CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: 26 October, 2010
Received: 27 October, 2010

Dear Ms. French:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

# Indication for Use

NOV 18 2010

510(k) Number (if known): K103162

Device Name: Elecsys PTH CalCheck 5

Indication For Use:

The Elecsys PTH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys PTH quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.

Prescription Use __X____ (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) K103162