

## 510(k) Summary

MAY 12 2011

K110613

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**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.

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Date Prepared: March 2, 2011

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**Device Name** Proprietary name: Elecsys Prolactin II CalCheck 5  
Common name: Prolactin II CalCheck 5  
Classification name: Single (specified) analyte controls (assayed and unassayed)

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**Predicate device** The Elecsys Prolactin II CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the cleared Elecsys DHEA-S CalCheck 5 (K103402).

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**Device Description** The Elecsys Prolactin II CalCheck 5 is a lyophilized product consisting of prolactin in an equine serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

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**Intended use** The Elecsys Prolactin II 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 Prolactin II reagent on the indicated Elecsys and cobas e immunoassay analyzers.

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## 510(k) Summary, Continued

**Comparison Table** The table below compares Elecsys Prolactin II CalCheck 5 with the predicate device, Elecsys DHEA-S CalCheck 5 (K103402).

Characteristic	Elecsys Prolactin II CalCheck 5 (Candidate Device)	Elecsys DHEA-S CalCheck 5 (K103402)
Intended Use	The Elecsys Prolactin II 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 Prolactin II reagent on the indicated Elecsys and cobas e immunoassay analyzers.	The Elecsys DHEA-S 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 DHEA-S reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Prolactin	DHEA-S
Levels	Five	Same
Format	Lyophilized	Same
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.	Same
Stability	<u>Unopened:</u> <ul style="list-style-type: none"> <li>• Store at 2-8°C until expiration date</li> </ul> <u>Reconstituted:</u> <ul style="list-style-type: none"> <li>• 20-25°C: 4 hours</li> </ul>	<u>Unopened:</u> <ul style="list-style-type: none"> <li>• Same</li> </ul> <u>Reconstituted:</u> <ul style="list-style-type: none"> <li>• Same</li> </ul>
Matrix	Equine serum matrix	Human serum matrix

**Performance Characteristics**

The Elecsys Prolactin II CalCheck 5 was evaluated for value assignment and stability.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Roche Diagnostics Corp.  
c/o Ms. Kelly Colleen O'Maine Adams  
Regulatory Affairs Consultant  
9115 Hague Road, Bldg. A  
Indianapolis, Indiana 46250-0416

**MAY 12 2011**

Re: k110613  
Trade Name: Elecsys Prolactin II Calcheck 5  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed).  
Regulatory Class: I, reserved  
Product Codes: JJX  
Dated: March 02, 2011  
Received: March 03, 2011

Dear Ms. O'Maine Adams:

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.

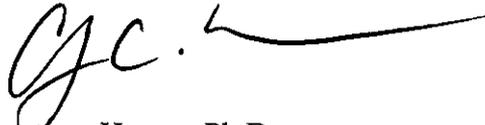
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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).

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If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CH', with a long horizontal line extending to the right.

Courtney 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

510(k) Number (if known): K110613

Device Name: Elecsys Prolactin II CalCheck 5

Indication For Use:

The Elecsys Prolactin II 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 Prolactin II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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)



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

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