K102086

510(k) Summary

NOV - 1 2010

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

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Date Prepared: June 30, 2010

Device Name

Proprietary name: Elecsys CA 125 II CalCheck 5
Common name: CA 125 II CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys CA 125 II CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys C-Peptide CalCheck 5 (K100810) and the Elecsys CA 125 II CalCheck (K003967).

Device Description

The Elecsys CA 125 II CalCheck 5 is a lyophilized product consisting of equine serum in level 1 and human serum matrix for levels 2-5. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys CA 125 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 CA 125 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.

Comparison Table The table below compares Elecsys CA 125 CalCheck 5 with the predicate devices, Elecsys C-Peptide CalCheck 5 (K100810) and the CA 125 II CalCheck (K003967).

Please note that the use of two predicates has been utilized for this submission based on previous FDA feedback to several of the most recently FDA-cleared CalCheck 5 products. The first predicate shows that the CA 125 II CalCheck 5 is substantially equivalent to another CalCheck 5 product. The Elecsys CA 125 II CalCheck 5 is also substantially equivalent to the second predicate, CA 125 II CalCheck, with several key similarities, especially the analyte. The shaded fields indicate similar characteristics between the candidate device and a predicate device.

Characteristic	**Elecsys C-Peptide CalCheck 5 (K100810)**	**Elecsys CA 125 II CalCheck 5 (Candidate Device)**	**Elecsys CA 125 II CalCheck (K003967)**
Intended Use	The Elecsys C-Peptide CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the serum and plasma assay range established by the Elecsys C-Peptide reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys CA 125 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 CA 125 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.	For use in verification of the calibration established by the Elecsys CA 125 II reagent on the Elecsys 2010 and 1010 Immunoassay analyzers.
Analyte	C-Peptide	CA 125	CA 125
Levels	Five	Five	Three
Format	Lyophilized	Same	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.	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: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 4 hours
Matrix	Equine serum matrix	Level 1: Equine serum Levels 2-5: Human serum matrix	Level 1: Equine serum Levels 2 & 3: Human serum matrix

Performance Characteristics The Elecsys CA 125 II CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

Roche Diagnostics
c/o Ms. Kelly French
Regulatory Affairs Consultant
Roche Professional Diagnostics
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Re: k102086
Trade/Device Name: Elecsys CA 125II CalCheck 5
Regulation Number: 21CFR§862.1660
Regulation Name: Quality control material, assayed and unassayed
Regulatory Class: Class I (Reserved)
Product Code: JJX
Dated: October 8, 2010
Received: October 12, 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k102086

NOV 0 1 2010

Device Name: Elecsys CA 125 II CalCheck 5

Indication For Use:

The Elecsys CA 125 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 CA 125 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.

Prescription Use __X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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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