K091601

SEP 25 2009

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

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Date Prepared: June 1, 2009

Device Name

Proprietary name: Elecsys Anti-CCP CalCheck

Common name: Anti-CCP CalCheck

Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys Anti-CCP CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys C-Peptide CalCheck (K040157).

Device Description

The Elecsys Anti-CCP CalCheck is a lyophilized product consisting of human antibodies to cyclic citrullinated peptide (CCP) in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. Once reconstituted, this solution is used to verify the calibration established by the Elecsys Anti-CCP reagent on the Elecsys and cobas e immunoassay analyzers.

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510(k) Summary, Continued

Intended use

For use in the verification of the calibration established by the Elecsys Anti-CCP reagent on the indicated Elecsys and cobas e immunoassay analyzers.

Comparison Table

The table below compares Elecsys Anti-CCP CalCheck with the predicate device, Elecsys C-Peptide Calcheck (K040157).

Characteristic	Elecsys C- Peptide CalCheck (K040157)	Elecsys Anti-CCP CalCheck
Intended Use	For use in the verification of the calibration established by the Elecsys C-Peptide reagent on the Elecsys and cobas e immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Anti-CCP reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Levels	Three	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Stability	Unopened: Store at 2–8°C until expiration date Reconstituted: 20–25°C : 4 hrs	Same
Matrix	Equine serum	Human serum

Performance Characteristics

The Elecsys Anti-CCP CalCheck was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Roche Diagnostics Corporation
c/o Sarah Baumann
9115 Hague Road
Box 50140
Indianapolis, IN 46250-0457

SEP 25 2009

Re: k091601
Trade/Device Name: Elecsys Anti-CCP CalCheck
Regulation Number: 21 CFR § 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: September 8, 2009
Received: September 14, 2009

Dear Sarah Baumann:

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).

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.
Acting 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):

Device Name: **Elecsys Anti-CCP CalCheck**

Indication For Use:

For use in the verification of the calibration established by the Elecsys Anti-CCP 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)

Carol C Benson

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

510(k) K091601