K121279

510(k) Summary

MAY 10 2012

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: April 27, 2012

Device Name

Proprietary name: Elecsys LH CalCheck 5
Common name: LH CalCheck 5
Classification: 21 CFR 862.1660, Single (specified) analyte controls (assayed and unassayed), Product Code: JJX

Predicate device

The Elecsys LH CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys N-MID Osteocalcin CalCheck 5 (K112104).

Device Description

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

Intended use

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

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Comparison Table The table below compares Elecsys LH CalCheck 5 with the predicate devices, Elecsys N-MID Osteocalcin CalCheck 5 (K112104).

Characteristic	Elecsys LH CalCheck 5 (Candidate)	Elecsys N-MID Osteocalcin CalCheck 5 (K112104)
Differences		
Intended Use	The Elecsys LH 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 Myoglobin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys N-MID Osteocalcin 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 N-MID Osteocalcin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	Luteinizing Hormone (LH)	Osteocalcin
Similarities		
Matrix	Human serum matrix	Same
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	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 4 hours	Same

Performance Characteristics The Elecsys LH CalCheck 5 was evaluated for value assignment and stability. See the following sections for details.

Traceability The Elecsys LH CalCheck 5 was standardized against the 2nd International Standard (NIBSC) 80/552.

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Value Assignment

Value assignment testing was conducted and must pass pre-defined acceptance criteria. For each Elecsys LH CalCheck 5 lot manufactured, the CalChecks are run in duplicate on at least three E170 analyzer measuring cells. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzer measuring cells) of the respective CalCheck. The target value for each CalCheck is the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range is calculated as ±30% of the assigned value for levels 2 through 5. The % CV is 10% for levels 2 through 5, while level 1 is free of the analyte. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

To ensure the values assigned using the master platform are transferrable and valid for the other instrument platforms, the same value assignment procedure is performed on the Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 analyzers. The assigned values obtained on the additional analyzers are compared to those obtained on the MODULAR ANALYTICES E170. The median value obtained on the four additional analyzers must be within 10% of the master platform assigned value (10% for between analyzer platform tolerances). After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the MODULAR ANALYTICS E170, Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 immunoassay analyzers.

Stability

Real-time and accelerated stability tests were conducted to establish the shelf-life and open-vial claims.

Open-Vial Stability After Reconstitution:
Real-time testing was performed and the data support the package insert claim that reconstituted Elecsys LH CalCheck 5 is stable up to 4 hours at 20-25°C.

Shelf-Life Stability:
The accelerated stability testing performed at 35°C supports an initial shelf-life claim of 18 months at 2-8°C. Real-time testing at 2-8°C is on-going to support a claim of 36 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAY 10 2012

Re: k121279
Trade Name: Elecsys LH CalCheck 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: April 27, 2012
Received: April 30, 2012

Dear Ms 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).

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/Medical Devices/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 H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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): K121279

Device Name: Elecsys LH CalCheck 5

Indication For Use:

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

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

510(k) 121279