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K090541

510(k) Summary – PreciControl Universal

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
Indianapolis, IN 46250
317-521-3723

Contact Person: Gail Sauers

Date Prepared: February 27, 2009

Submission purpose

Roche Diagnostics hereby submits this Traditional 510(k) device modification to provide notification of changes to our control material, Elecsys PreciControl Universal (PCU).

PreciControl Universal is used for quality control of Elecsys immunoassays on the Elecsys and cobas e immunoassay analyzers. This product contains control material for numerous Elecsys assays in one convenient solution.

Changes to PCU consist of the addition of Carcinoembryonic antigen (CEA) control and total (free + complexed) Prostate-Specific Antigen (PSA) to extend the current functionality.

Device Name

Proprietary name: Elecsys PreciControl Universal.

Common name: PreciControl Universal

Classification name: Multi-Analyte Controls, All Kinds (assayed and Unassayed)

Device Description

The Elecsys PreciControl Universal is a lyophilized product consisting of added antigens in a human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

Intended use

Elecsys PreciControl Universal is used for quality control of Elecsys immunoassays on the Elecsys and cobas e immunoassay analyzers.

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Predicate Device

The Elecsys PreciControl Universal is substantially equivalent to the currently marketed Elecsys PreciControl Universal (PCU) K051687.

Device Comparison

The table below indicates the similarities between the modified Elecsys PreciControl Universal and the predicate PCU, K051687.

Similarities

Characteristics	Elecsys PreciControl Universal	Predicate Device Elecsys PreciControl Multianalyte (K051687)
Intended Use	Elecsys PreciControl Universal is used for quality control of Elecsys immunoassays on the Elecsys and cobas e immunoassay analyzers	Elecsys PreciControl Universal is used for quality control of the Elecsys immunoassays on Elecsys immunoassay systems.
Reagent Format	Same	Lyophilized, based on human serum in two concentration ranges.
Matrix	Same	Human serum matrix
Stability	Same	Unopened : Store at 2-8°C until expiration date Reconstituted (except for Insulin): • on the analyzers at 20-25 °C: up to 5 hrs • At 2-8°C: 3 days • At -20°C: 1 month (freeze only once) Reconstituted for Insulin: • on the analyzers at 20-25 °C: up to 5 hrs • 20-25 °C: up to 5 hrs • at -20: 1 month (freeze only once)

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510(k) Summary - continued

Similarities - continued

Characteristics	Elecsys PreciControl Universal	Predicate Device Elecsys PreciControl Multianalyte (K051687)
Handling	Same	Reconstitute with exactly 3.0 mL of distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.

Performance Characteristics

The Elecsys PreciControl Universal was evaluated for value assignment and stability.

Device Comparison

The table below indicates the differences between the modified Elecsys PreciControl Universal and the predicate PCU, K051687.

Differences

Characteristics	Elecsys PreciControl Universal	Predicate Device Elecsys PreciControl Multianalyte (K051687)
Analyzer System	Elecsys immunoassay and cobas e analyzers. Elecsys 2010 Cobas e 411 MODULAR ANALYTICS E170 Cobas e 601	Elecsys immunoassay analyzers. Elecsys 1010 Elecsys 2010 MODULAR ANALYTICS E170

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Differences - continued

Characteristics	Elecsys PreciControl Universal	Predicate Device Elecsys PreciControl Multianalyte (K051687)
Analyte Concentration	• AFP (human cell culture) approx. 10-50 IU/ml • Cortisol (vegetable) approx. 359-500 nmol/L • DHEAs (synthetic) approx. 200-500 µg/dL • Estradiol (synthetic) approx. 100-500 pg/mL • FSH (human) approx. 10-45 mIU/mL • fT3 (synthetic) approx. 6-25 pmol/L • fT4 (synthetic) approx. 12-35 pmol/L • hCG (human) approx. 5-40 mIU/mL • IgE (human) approx. 70-300 U/mL • Insulin, (human, recomb.) approx. 25-80 µU/mL • LH (human) approx. 9-50 mIU/mL • Progesterone (vegetable) approx. 8-20 ng/mL • Prolactin (human recombinant) approx. 233-848 µIU/mL • SHBG (human) endogenous • T3 (synthetic) approx. 2-6 nmol/mL • T4 (synthetic) approx. 90-170 nmol/L • Testosterone (vegetable) approx. 6-2.5 ng/mL • Thyroglobulin * (human) approx. 25-100 ng/mL • TSH (human) approx. 1-8.5 µIU/mL • T-Uptake approx. (human) 1-.75 TBI • CEA (human cell culture) approx. 5-50 ng/mL • tPSA (human) approx. 1-40 ng/mL • S100 * (bovine) approx. .2-2.5 ng/mL * not included in US labeling	• AFP (human cell culture) approx. 10-50 IU/ml • B_{12} (synthetic) approx. 1-.5 ng/mL • Cortisol (vegetable) approx. 13-30 µg/dL • DHEAs (synthetic) approx. 200-500 µg/dL • Estradiol (synthetic) approx. 100-500 pg/mL • Ferritin (human) approx. 150-30 ng/mL • Folate (synthetic) approx. 12-5.5 ng/mL • FSH (human) approx. 10-45 mU/mL • fT3 (synthetic) approx. 4-16 pg/mL • fT4 (synthetic) approx. .9-2.7 ng/dL • hCG (human) approx. 10-40 mU/mL • IgE (human) approx. 70-300 U/mL • Insulin, (human, recomb.) approx. 25-80 µU/mL • LH (human) approx. 9-50 mU/mL • Progesterone (vegetable) approx. 8-20 ng/mL • Prolactin (human recombinant) approx. 11-40 ng/mL • SHBG (human) endogenous • T3 (synthetic) approx. 1.5-4 ng/mL • T4 (synthetic) approx. 7-13 µg/dL • Testosterone (vegetable) approx. 6-2.5 ng/mL • TSH (human) 1-8.5 µU/mL • T-Uptake (human) 1.1-.75 TBI

Roche

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Roche Diagnostics
ATTN: Ms. Gail Sauers
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250-0416

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Re: k090541
Trade/Device Name: Elecsys PreciControl Universal
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I (Reserved)
Product Code: JJY
Dated: May 27, 2009
Received: June 02, 2009

Dear Ms. Sauers:

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 PreciControl Universal

Indication For Use:

Elecsys PreciControl Universal is used for quality control of Elecsys immunoassays on 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)

voting

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

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