K 051687

510(k) Summary

JUL 25 2005

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: Corina Harper

Date Prepared: June 22 , 2005

Device Name

Proprietary name: Elecsys® PreciControl Universal

Common name: PreciControl Universal

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

Predicate Device

The Elecsys® PreciControl Universal is substantially equivalent to the currently marketed Elecsys® PreciControl MultiAnalyte (K033937).

Device Description

The Elecsys® PreciControl Universal is a lyophilized product consisting of added antigens in 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 the Elecsys® immunoassays on Elecsys® immunoassay systems.

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Comparison to Predicate Device

The Elecsys® PreciControl Universal is substantially equivalent to the currently marketed Elecsys® PreciControl MultiAnalyte (K033937). The table below compares Elecsys® PreciControl Universal with the predicate device, Elecsys® PreciControl MultiAnalyte (K033937).

Similarities

Characteristics	Elecsys® PreciControl Universal	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)
Intended Use	Elecsys® PreciControl Universal is used for quality control of the Elecsys® immunoassays on the Elecsys® immunoassay systems.	Elecsys® PreciControl MultiAnalyte is used for quality control of the Elecsys® C-Peptide and Elecsys® Insulin immunoassays on the Elecsys® immunoassay systems.
Levels	Two	Same
Format	Lyophilized	Same

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Comparison to Predicate Device (continued) - **Similarities**

Characteristics	Elecsys® PreciControl Universal	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)
Handling	Reconstitute with exactly 3.0 mL of distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Reconstitute with exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute, and then mix gently.
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted (except for Insulin): • on the analyzers at 20-25°C: up to 5 hrs • 20 – 25°C: up to 8 hrs • at 2-8°C: 3 days • at -20°C: 1 month (freeze only once) Reconstituted of Insulin: • on the analyzers at 20-25°C: up to 5 hrs • 20 – 25°C: up to 5 hrs • at -20°C: 1 month (freeze only once)	Unopened: • Same Reconstituted: • on the analyzers at 20-25°C: up to 3 hrs • at -20°C: 1 month (freeze only once) • after thawing: use only once

Differences

Characteristics	Elecsys® PreciControl Universal	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)
Matrix	Human serum matrix with added Antigens (see Table 1: "Matrix Compositon")	Equine serum with added C-Peptide and insulin

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Matrix Composition

The table below lists all active ingredients for Elecsys® PreciControl Universal.
The active ingredients are spiked into a buffered human serum matrix

Table 1

	Component	Concentration
Reactive Components	AFP (human, cell culture) Cortisol (synthetic) DHEAS (synthetic) Estradiol (synthetic) Ferritin (human) Folate (synthetic) FSH (human) L-Thyroxin (synthetic) hCG (human) IgE (human) Insulin (human, recomb.) LH (human) Progesterone (vegetable) Prolactin (human) Testosterone (vegetable) SHBG (human) T3 (synthetic) TSH (human, recomb.) Vitamin B12 (synthetic)	please refer to target value sheet of package insert

Performance Characteristics

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 25 2005

Ms. Corina Harper, RAC
Regulatory Consultant
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: k051687
Trade/Device Name: Elecsys® PreciControl Universal
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: June 22, 2005
Received: June 24, 2005

Dear Ms. Harper:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051687

Device Name:

Elecsys® PreciControl Universal

Indications For Use:

Elecsys® PreciControl Universal is used for quality control of the Elecsys® immunoassays on the Elecsys® immunoassay systems.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051687