K092320

510(k) Summary—Elecsys PreciControl ThyroAB

NOV - 3 2009

Introduction

In accordance with 21 CFR 807.92, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

Submitter Name, Address, Contact

Roche Diagnostics
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Date Prepared: July 30, 2009

Submission Purpose

PreciControl ThyroAB is used for quality control of specified 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 PreciControl ThyroAB consist of the addition of anti-thyroperoxidase (Anti-TPO) and anti-thyroglobulin (Anti-TG) antibodies to extend the current functionality.

Device Name

Proprietary name: Elecsys PreciControl ThyroAB
Common name: PreciControl ThyroAB
Classification name: Multi-Analyte Controls, All Kinds (assayed and Unassayed)

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510(k) Summary—Elecsys PreciControl ThyroAB, Continued

Device Description

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

Intended Use

Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Predicate Device

The modified Elecsys PreciControl ThyroAB is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys PreciControl ThyroAB (K080092).

Device Comparison—Similarities

The table below presents the similarities between the modified Elecsys PreciControl ThyroAB and the predicate device, Elecsys PreciControl ThyroAB (K080092).

Characteristic	Predicate Device Elecsys PreciControl ThyroAB (K080092)	Elecsys PreciControl ThyroAB
Analyzer System	Elecsys and cobas e immunoassay analyzers: -Elecsys 2010 -MODULAR ANALYTICS E170 -cobas e 411 -cobas e 601	Same
Format	Lyophilized	Same
Matrix	Human Serum	Same

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Device Comparison—Differences

The table below presents the differences between the modified Elecsys PreciControl ThyroAB and the predicate device, Elecsys PreciControl ThyroAB (K080092).

Characteristic	Predicate Device Elecsys PreciControl ThyroAB (K080092)	Elecsys PreciControl ThyroAB
Intended use	Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR immunoassay on the Elecsys and cobas e immunoassay analyzers.	Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Analyte concentration	Anti-TSHR (IU/L): Level 1 = 4 Level 2 = 16	Anti-TSHR (IU/L): Level 1 = 4 Level 2 = 16 Anti-TPO (IU/mL): Level 1 = 35 Level 2 = 100 Anti-TG (IU/mL): Level 1 = 100 Level 2 = 200
Antibody source and type	Anti-TSHR: Human monoclonal	Anti-TSHR: Human monoclonal Anti-TPO: Sheep polyclonal Anti-TG: Sheep polyclonal
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

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Device Comparison—Differences (continued)

The table below presents the differences between the modified Elecsys PreciControl ThyroAB and the predicate device, Elecsys PreciControl ThyroAB (K080092).

Characteristic	Predicate Device Elecsys PreciControl ThyroAB (K080092)	Elecsys PreciControl ThyroAB
Stability	Unopened : Store at 2-8°C until expiration date Reconstituted: on the analyzer at 20-25°C: up to 3 hrs at -20°C: 3 months (freeze only once) After Thawing: use only once.	Unopened : Store at 2-8°C until expiration date Reconstituted: on the analyzer at 20-25 °C: up to 5 hrs at -20°C: 1 month (freeze only once) or at 2-8°C for 3 day (for Anti-TG & Anti-TPO only)

Performance Characteristics

The Elecsys PreciControl ThyroAB was evaluated for value assignment, stability, and duration of reconstitution.

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
c/o Ms. Sarah Baumann
Regulatory Affairs Cousultant
9115 Hague Road, PO Box 50410
Indianapolis, Indiana 46250-4016

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Re: k092320
Trade Name: Elecsys PreciControl-ThyroAB
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: September 30, 2009
Received: October 01, 2009

Dear Ms. 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.
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): K092320

Device Name: Elecsys PreciControl ThyroAB

Indication For Use:

Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the 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

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