510(k) Summary

FEB 1 1 2011 K 103171

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: October 26, 2010

Device name

Proprietary name: Elecsys® Anti-TPO CalSet
Common name: Anti-TPO CalSet
Classification name: Calibrator, Secondary

Predicate device

The Elecsys® Anti-TPO CalSet is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys® Anti-TPO CalSet (cleared as part of the Elecsys® Anti-TPO test system on K051890).

Device description

The Elecsys® Anti-TPO CalSet is a lyophilized product consisting of sheep anti-TPO antibodies in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

Elecsys Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and **cobas e** immunoassay analyzers.

Reason for submission

The Elecsys® Anti-TPO CalSet is being changed from a liquid to lyophilized material. The formulation of the candidate device (Elecsys® Anti-TPO CalSet, lyophilized) is identical to that of the predicate device, Elecsys® Anti-TPO CalSet (liquid, and cleared as part of the Elecsys® Anti-TPO test system on K051890).

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510(k) Summary, Continued

Comparison table

The Elecsys® Anti-TPO CalSet is currently sold to customers as part of the Elecsys® Anti-TPO assay kit. Upon clearance of the modified Elecsys® Anti-TPO CalSet device, it will be packaged and sold separately from the Elecsys® Anti-TPO assay kit.

Table 1 below compares Elecsys® Anti-TPO CalSet (K103171) with the predicate device, Elecsys® Anti-TPO CalSet (cleared as part of the Elecsys® Anti-TPO Test System on K051890).

Table 1. Comparison of Candidate and Predicate Devices

Characteristic	Elecsys® Anti-TPO CalSet (Candidate Device, K103171)	Elecsys® Anti-TPO CalSet (K051890)
Intended Use	Elecsys Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and **cobas e** immunoassay analyzers.	The Elecsys Anti-TPO immunoassay is for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases. The electrochemiluminescence assay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.[1]
Material Form (Format)	Lyophilized	Liquid
Analyte	Anti-TPO Antibodies (Sheep)	Same
Traceability	NIBSC (National Institute for Biological Standards and Controls) 66/387 International Standard	Same
Matrix	Human serum	Same
Levels and Corresponding Concentrations	Two Calibrator 1: approx. 35.0 IU/mL Calibrator 2: approx. 350 IU/mL	Two Calibrator 1: approx. 35.0 IU/mL Calibrator 2: approx. 350 IU/mL
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • at 2-8°C: 7 days • at -20 °C: 8 weeks (freeze only once) • on the analyzers at 20-25 °C: use only once	Unopened: • Store at 2-8°C until expiration date Opened: • at 2-8°C: 6 weeks • at 20-25 °C on Elecsys 1010/2010: up to 5 hours • MODULAR ANALYTICS E170: use only once

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[1] The Elecsys® Anti-TPO CalSet was originally cleared as part of the Elecsys® Anti-TPO test system on K051890 and is currently sold to customers as part of the Elecsys® Anti-TPO assay kit. As such, the Intended Use of the assay reagent kit is listed in Table 1. Upon clearance of the modified Elecsys® Anti-TPO CalSet device, it will be packaged and sold separately from the assay kit.

510(k) Summary, Continued

Comparison table, continued

The Elecsys® Anti-TPO CalSet is currently sold to customers as part of the Elecsys® Anti-TPO assay kit. Upon clearance of the modified Elecsys® Anti-TPO CalSet device, it will be packaged and sold separately from the Elecsys® Anti-TPO assay kit.

Table 1 below compares Elecsys® Anti-TPO CalSet (K103171) with the predicate device, Elecsys® Anti-TPO CalSet (cleared as part of the Elecsys® Anti-TPO Test System on K051890).

Table 1. Comparison of Candidate and Predicate Devices, continued

Characteristic	Elecsys® Anti-TPO CalSet (Candidate Device, K103171)	Elecsys® Anti-TPO CalSet (K051890)
Handling	Dissolve carefully the contents of one bottle by adding exactly 1.5 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottles supplied. Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25°C. Perform **only one** calibration procedure per aliquot. If necessary, freeze in aliquots; see section on MODULAR ANALYTICS E170 and **cobas e** 601 analyzers. MODULAR ANALYTICS E170 and **cobas e** 601analyzers: Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the reconstituted calibrator into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots for later use at -20°C. Perform **only one** calibration procedure per aliquot.	The reagents in the kit are ready for use and supplied in the bottles compatible with the system. Elecsys 1010/2010 analyzers: The Elecsys calibrators Cal1 and Cal2 and the Elecsys controls[2] PC A-TPO1 and PC A-TPO2 should only be left on the analyzers at 20-25°C during calibration/quality control. After use, close the bottles as soon as possible and store at 2-8°C. Ensure that no calibration and control solution is trapped in the opened snap-cap. Because of possible evaporation effects, not more than 5 calibration/quality control procedures per bottle set should be performed. MODULAR ANALYTICS E170 analyzer: Unless the entire volume is necessary for calibration and quality control on the analyzer, transfer aliquots of the ready-for-use calibrators and controls into empty snap-cap bottles (CalSet Vials/ControlSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots for later use at 2-8°C. Perform **only one** calibration or control procedure per aliquot. All information required for correct operation is read in via the respective reagent barcodes.

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[2] The control materials originally sold with the Elecsys® Anti-TPO test system (PC A-TPO1 and PC A-TPO2) are no longer included in the assay kit. A new control material, Elecsys® PreciControl ThyroAB, was cleared on K092320 and includes the appropriate levels of anti-TPO for quality control of the Elecsys® Anti-TPO assay.

510(k) Summary, Continued

Performance characteristics	The Elecsys® Anti-TPO CalSet was evaluated for value assignment, stability, and reconstitution.
Conclusion	The data demonstrate that the performance of the Elecsys® Anti-TPO CalSet is substantially equivalent to that of the predicate device, Elecsys® Anti-TPO CalSet (cleared as part of the Elecsys® Anti-TPO Test System on K051890).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 1 1 2011

Roche Diagnostics
c/o Ms. Sarah Baumann
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250-0416

Re: k103171
Trade/Device Name: Elecsys® Anti-TPO CalSet
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX
Dated: January 06, 2011
Received: January 07, 2011

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 class II (Special Controls), 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). 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K103171

Device Name: Elecsys Anti-TPO CalSet

Indications for Use: Elecsys Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and **cobas e** immunoassay analyzers.

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

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

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

Reena Philip

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

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