K051890

AUG 4 - 2005

510(k) Summary - COBAS Elecsys® anti-TPO

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 Rd
Indianapolis IN 46250
(317) 521-3544

Contact person: Kay A. Taylor

Date prepared: July 11, 2005

Device Name

Proprietary name: Roche Diagnostics COBAS Elecsys® Anti-TPO

Common name: anti-TPO Assay

Classification name: System, Test, Thyroid Autoantibody

Device description

The COBAS Elecsys® Anti-TPO Test System is based on a competitive immunoassay with streptavidin microparticles and electrochemiluminescence detection. First and second incubations are nine minutes in duration. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, unbound substances are removed. Voltage is applied to the electrode inducing chemiluminescent emission which is measured by a photomultiplier. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

510(k) Summary - COBAS Elecsys® anti-TPO, continued

Intended use

Immunoassay 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 immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Predicate Device

The COBAS Elecsys® Anti-TPO Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Elecsys Anti-TPO (K000155).

Device Comparison

The table below illustrates the similarities between the Elecsys Anti-TPO (K000155) and the COBAS Elecsys Anti-TPO (modified device).

Topic	Elecsys® Anti-TPO (K000155)	COBAS Elecsys® Anti-TPO (Modified Device)
Intended use	for the quantitative determination of antibodies to thyroid peroxidase in human serum and plasma.	same
Indication for use	as an aid in the diagnosis of autoimmune thyroid diseases	same
Sample type	human serum and plasma	same
Dilution performance	Autoantibodies are heterogenous and this may lead to non-linear dilution phenomena for certain individual samples.	same
Traceability / Standardization	WHO 66/387	same
Test Principle	Competitive chemiluminescence	Same

510(k) Summary - COBAS Elecsys® anti-TPO, continued

Topic	Elecsys® Anti-TPO (K000155)	COBAS Elecsys® Anti-TPO (Modified Device)
Measuring range	5 – 600 IU/ml	Same
Reagent Stability	Unopened: - at 2-8°C up to the expiration date. Opened: - at 2-8°C up to six weeks. - on E170 / 2010: two weeks - on 1010: one weeks store alternately in refrigerator and on analyzer – at ambient temperature 20-25 °C; up to 20 hours in total).	Same
Limitations	No interference from; Bilirubin up to 66 mg/dl Hemolysis up to 1.5 g/dl Lipemia up to 2100 mg/dl Biotin up to 60 ng/ml Rheumatoid factors up to 1500 U/ml	 Same Same Same Biotin up to 10 ng/ml Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Ms Kay A Taylor
Regulatory Affairs Principal
Centralized Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250

AUG 4 - 2005

Re: k051890
Trade/Device Name: Roche Diagnostics Cobas Elecsys® anti-TPO Test System
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid antibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO
Dated: July 11, 2005
Received: July 12, 2005

Dear Ms. Taylor:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K051890**

Device Name: **cobas Elecsys Anti-TPO**

Indications For Use:

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 immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Prescription Use **XXXXX** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051890