APR 25 2005

K050387

510(k) Summary - Elecsys® PreciControl Tumor Marker

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 Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Kay A. Taylor Date prepared: February 14, 2005
Device Name	Proprietary name: Roche Diagnostics Elecsys® PreciControl Tumor Marker Common name: Quality Control Material Classification name: Multi-analyte Controls (assayed and unassayed)
Device description	PreciControl Tumor Marker contains lyophilized control serum based on human serum. The concentrations are in two clinically relevant ranges. The controls are used for monitoring the accuracy and precision of Elecsys immunoassays.
Intended use	PreciControl Tumor Marker is used for quality control of Elecsys immunoassays on Elecsys immunoassay systems.
Predicate Device	We claim substantial equivalence to the currently marketed Elecsys® PreciControl Tumor Marker (K972235).

510(k) Summary - Elecsys® PreciControl Tumor Marker,
continued

Device Comparison

The table below indicates the similarities between the modified Elecsys® PreciControl Tumor Marker and the current device.

Topic	Elecsys® PreciControl Tumor Marker (K972235)	Elecsys® PreciControl Tumor Marker (Modified Device)
Intended Use	PreciControl Tumor Marker is used for quality control of Elecsys immunoassays using the Elecsys immunoassay systems (Elecsys 2010, 1010 and others of the Elecsys family of instruments).	PreciControl Tumor Marker is used for quality control of Elecsys immunoassays on Elecsys immunoassay systems.
Analyzer System	Elecsys® immunoassay analyzers	Same
Reagent Format	lyophilized, based on human serum	Same
Analyte Concentration PC TM1 / PC TM2	AFP: approx. 8 & 100 IU/ml CEA: approx. 5 & 50 ng/ml CA 15-3 II: approx. 20 & 100 U/mL CA 125 II: approx. 35 & 100 U/mL Ferritin: approx. 25 & 200 ng/mL fPSA: approx. 1 & 10 ng/mL tPSA: approx. 4 & 40 ng/mL	AFP: approx. 8 & 100 IU/ml CEA: approx. 5 & 50 ng/ml CA 15-3 II: approx. 20 & 100 U/mL CA 125 II: approx. 35 & 100 U/mL Ferritin: approx. 25 & 200 ng/mL fPSA: approx. 1 & 10 ng/mL tPSA: approx. 4 & 40 ng/mL CA 19-9: approx. 20 & 100 U/mL,
Stability	@ 2-8° C • unopened until expiration date • opened for 2 weeks @ 20-25° C • on the analyzers, up to 5 hours • 24 hours @ -20° C • 1 month (freeze only once) months at -20° C (only freeze once)	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 25 2005

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

Re: k050387
Trade/Device Name: Elecsys PreciControl Tumor Marker
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 14, 2005
Received: February 15, 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. 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/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M.D., PhD
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

510(k) Number (if known): K050387

Device Name: **Elecsys PreciControl Tumor Marker**

Indications For Use:

PreciControl Tumor Marker is used for quality control of Elecsys immunoassays on Elecsys immunoassay systems.

The controls are used for monitoring the accuracy and precision of Elecsys immunoassays.

Prescription Use XXX (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) K050387