K043095

NOV 2 3 2004

510(k) Summary - Elecsys® AFP CalSet II

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: November 8, 2004
Device Name	Proprietary name: Elecsys® AFP CalSet II Common name: Calibrator Classification name: Calibratory, secondary
Device description	The Elecsys® AFP CalSet II consists of a lyophilized human serum matrix with added AFP in two concentrations.
Intended use	The Elecsys AFP CalSet II is used for calibrating the quantitative AFP assay on the Elecsys immunoassay systems.
Predicate Device	We claim substantial equivalence to the currently marketed Elecsys® AFP Calset. (K981282).

510(k) Summary - Elecsys® AFP CalSet II, continued

Reagent Summary

The following table describes the similarities and differences between the Elecsys® AFP CalSet II and the Elecsys AFP CalSet.

Topic	Elecsys® AFP CalSet (K981282)	Elecsys® AFP CalSet II (Modified Device)
Intended Use	The Elecsys AFP CalSet is used for calibrating the quantitative AFP assay on the Elecsys immunoassay systems.	The Elecsys AFP CalSet II is used for calibrating the quantitative AFP assay on the Elecsys immunoassay systems.
Matrix	Buffer	Human serum
Storage Form	Liquid	Lyophilized
Levels	Low: approx. 5-6 ng/ml High: approx. 50-60 ng/ml	Same
Standardization	Standardized against the 1st IRp WHO reference standard 72/225.	Same
Stability	12 wks at 2-8°C: 20-25°C: up to 5 hours on 1010/2010 use only once on E170	6 wks at 2-8°C: 6 wks at -20°C: (freeze once) 20-25°C: up to 5 hours on 1010/2010 use only once on E170

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 23 2004

Ms Kay Taylor MT (ASCP), RAC
Regulatory Program Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k043095
Trade/Device Name: Roche Diagnostics Elecsys® AFP CalSet II
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 8, 2004
Received: November 9, 2004

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) 276-3084. 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 Statement

510(k) Number (if known): N/A K043095

Device Name: Elecsys® AFP CalSet II

Indications For Use:

The Elecsys AFP CalSet II is used for calibrating the quantitative AFP assay on the Elecsys immunoassay systems.

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

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

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

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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