K981282

MAY 1 1998

510(k) Summary

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.

1. Submitter name, address, contact

Roche Diagnostics/Boehringer Mannheim Corporation
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94566-0900
(925) 730-8215

Contact Person: Patricia M. Klimley
Date Prepared: April 6, 1998

2. Device name

Proprietary name: Elecsys® AFP Assay

Common name: Electrochemiluminescence assay for the determination of Alpha Fetoprotein (AFP).

Classification name: Kit, Test , Alpha Fetoprotein

3. Predicate device

The Roche Diagnostics/Boehringer Mannheim Elecsys® AFP on Elecsys® 1010 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Elecsys® AFP on Elecsys® 2010.

4. Device Description

The Elecsys® test principle is based on sandwich principle. Total duration of assay: 18 minutes (37° C).
- 1st incubation (9 minutes): Sample (30 µL), biotinylated monoclonal AFP-specific antibody (60 µL), and a monoclonal AFP-specific antibody labeled with a ruthenium complex (60 µL) react to form a sandwich complex.
- 2nd incubation (9 minutes): After addition of streptavidin-coated microparticles (50 µL), the complex is bound to the solid phase via interaction of biotin and streptavidin.

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4. Device Description	•The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier (0.4 second read frame). •Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.
5. Intended use	Immunoassay for the in vitro quantitative determination of alpha fetoprotein (AFP) in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Diagnostics/Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.
6. Comparison to predicate device	The Roche Diagnostics/Boehringer Mannheim Elecsys® AFP Assay has been approved for use on the Elecsys 2010 immunoassay analyzer (K973351). The application of the Elecsys® AFP Assay on the Elecsys 1010 immunoassay analyzer is substantially equivalent to the same assay (Elecsys AFP Assay) on the Elecsys 2010.

The following table compares the Elecsys® AFP Assay on Elecsys® 1010 with the predicate device, Elecsys® AFP Assay on Elecsys® 2010 . Specific data on the performance of this test for both the Elecsys 1010 and 2010 have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in attachment 6 will be replaced upon the clearance of this premarket notification submission with the combined Elecsys 2010 and 1010 insert (attachment 5).

Similarities:

•Intended Use: Immunoassay for the in vitro quantitative determination of Alpha Fetoprotein (AFP). The assay is further indicated for the serial measurement of AFP to aid in the management of cancer patients.

•Assay range: 0.5-1000 IU/mL

•Assay methodology: Sandwich immunoassay

•Kit (cat. No.) also cleared for use on the Elecsys 2010 (K973351)

•Sample and reagent volumes

•Package insert

•Performance specifications

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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® 1010	Elecsys® 2010
Instrument required	Elecsys 1010	Elecsys 2010
Instrument Type	Batch	Random access
Reagent Storage Temp (C)	Ambient Temperature	20° C

Performance Characteristics:

Feature	Elecsys® 1010			Elecsys® 2010		
Precision Level	Modified NCCLS (IU/mL): HS1	HS2	HS3	Modified NCCLS (IU/mL): HS1	HS2	HS3
N	60	60	60	60	60	60
Within-Run	9.81	50.67	607.39	12.8	42.6	566
%CV	1.01	1.02	1.52	2.0	1.5	2.0
Total	9.81	50.67	607.39	12.8	42.6	566
%CV	2.25	2.69	4.61	3.1	2.4	2.8
	Modified NCCLS IU/mL):			Modified NCCLS (IU/mL):		
	Control 1	Control 2		Control 1	Control 2	
N	60	60		60	60	
Within-Run	7.72	86.81		8.01	86.8	
%CV	1.29	1.39		2.8	2.2	
Total	7.72	86.81		8.01	86.8	
%CV	1.90	2.29		3.4	2.7	

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Performance Characteristics:

Feature	Elecsys® 1010	Elecsys® 2010
Lower Detection Limit	0.5 IU/mL	0.5 IU/mL
Linearity	0.5 - 1000 IU/mL (with a deviation from a linear line of ±10%)	0.5 - 1000 IU/mL (with a deviation from a linear line of ±10%)
Method Comparison	Vs Elecsys 2010 Least Squares y =0.980x + 0.639 r=0.992 N=153 Passing/Bablok y =1.031x - 0.208 r=0.992 N=153	
Hook Effect	No Hook Effect up to 1,000,000 IU/mL AFP	No Hook Effect up to 1,000,000 IU/mL AFP

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Ms. Patricia M. Klimley
Manager, Elecsys Regulatory Affairs
Roche Diagnostics/
Boehringer Mannheim Corporation
Laboratory Diagnostics
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

Re: K981282
Trade Name: Elecsys® AFP Assay
Regulatory Class: II
Product Code: LOJ
Dated: April 6, 1998
Received: April 8, 1998

Dear Ms. Klimley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~N/A~~ K981282

Device Name: Elecsys® AFP Assay

Indications For Use:

Immunoassay for the in vitro quantitative determination of alpha-fetoprotein in human serum and plasma to aid in the management of patients with non-seminomatous germ cell tumors.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter E Mahan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981282