K973112

OCT 10 1997

BOEHRINGER MANNHEIM CORPORATION

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

Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, CA 94524-4117
(510) 674 - 0690, extension 8413
Fax: (510) 687-1850
Contact Person: Yvette Lloyd

Date Prepared: August 14, 1997

2. Device name

Proprietary name: Elecsys® Digoxin Assay

Common name: Electrochemiluminescent immunoassay for the determination of Digoxin.

Classification name: System, Test, Digoxin

3. Predicate device

The Boehringer Mannheim Elecsys® Digoxin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott TDx® Digoxin II Assay (K882233).

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4. Device Description

Competition principle. Total duration of assay: 18 minutes, 37 °C.

•1st incubation (9 minutes): By incubating the sample (10 µL) with a digoxin-specific ruthenylated** antibody (80 µL), an immunocomplex is formed, the amount of which is dependent upon the analyte concentration in the sample.

•2nd incubation (9 minutes): After addition of streptavidin-coated microparticles (30 µL) and a digoxin derivative labeled with biotin (80 µL), the still-vacant sites of the ruthenylated antibodies become occupied, with the formation of an antibody-hapten complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.

•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.

**Tris(2,2'-bipyridyl)ruthenium(II) complex ($Ru(bpy)^{2+}_3$)

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5. Intended use

Immunoassay for the in vitro quantitative determination of Digoxin in human serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® Digoxin Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott TDx® Digoxin II Assay (K882233).

The following table compares the Elecsys® Digoxin Assay with the predicate device, Abbott TDx® Digoxin II Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Intended Use: Immunoassay for the in vitro quantitative determination of Digoxin
- Sample type: Serum and plasma
- Assay range: 0 - 5 ng/mL

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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® Digoxin	TDx Digoxin II
Reaction test principle	Electrochemiluminescence	Fluorescence Polarization
Instrument required	Elecsys® 2010	Abbott TDx

Performance Characteristics:

Feature	Elecsys® Digoxin			TDx Digoxin II		
Precision	Modified NCCLS (ng/mL):			NCCLS (ng/mL):		
Level	Level 1	Level 2	Pool 1	Low	Mid	High
N	60	60	60	50	50	50
Within run	1.34	3.08	0.85	0.70	1.44	3.66
%CV	3.57	3.33	5.22	5.75	3.15	1.87
Total	1.34	3.08	0.85	0.70	1.44	3.66
%CV	5.24	4.09	7.69	7.67	3.98	1.91

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® Digoxin	TDx Digoxin II
Lower Detection Limit	0.15 ng/mL	0.2 ng/mL
Linearity	0.15 - 5 ng/mL	0.0 - 5.0 ng/mL
Method Comparison	Vs Abbott TDx Digoxin Least Squares y =1.03X + 0.10 r=0.9847 N=357 Passing Bablock: y=1.06X + 0.06 r=0.9847 N=357	Vs Baxter Dade Stratus y =0.94x + 0.08 r=0.962 N=200

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® Digoxin	TDx Digoxin II
Interfering substances	No interference at: (within 0.15 ng/ml at digoxin level ≤1.5 ng/ml or within ±10% at digoxin level > 1.5 ng/ml.)	No interference at:
Bilirubin		
Hemoglobin	65 mg/dL	20 mg/dL
Lipemia	1000 mg/dL	1000 mg/dL
Rheumatoid Factor	1500 mg/dL	2500 mg/dL
Biotin	1630 IU/mL	N/A
	100 ng/ml	N/A
Specificity	% Cross-reactivity	% Cross-reactivity
Digoxigenin	14.28	up to 200
Digoxingenin-Mono-Digitoxiside	55.31	up to 200
Digitoxin-Bis-Digitoxiside	74.64	up to 200
Digitoxin	1.13	4.8
Cortisol	<0.01	<1.0
Canrenone	<0.01	<1.0
DHEA	0.01	<1.0
16-β-DHEA	<0.01	not tested
Furosemide	<0.01	<1.0
Ouabain	<0.01	<1.0
Prednisolone	<0.01	<1.0
Prednisone	<0.01	<1.0
Progesterone	<0.01	<1.0
17-Hydroxyprogesterone	<0.01	<1.0
Spironolactone	<0.01	<1.0
Testosterone	<0.01	<1.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Yvette Lloyd
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
4300 Hacienda Drive
Pleasanton, California 94588-2722

OCT 10 1997

Re: K973112
Trade Name: Elecsys® Digoxin Assay
Regulatory Class: II
Product Code: KXT
Dated: August 14, 1997
Received: August 20, 1997

Dear Ms. Lloyd:

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

Device Name: Elecsys® Digoxin Assay

Indications For Use:

Immunoassay for the in vitro quantitative determination of digoxin in human serum and plasma. Measurements are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure proper therapy.

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

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973772