MAY 14 1997 K970881

510(k) Summary

BOEHRINGER MANNHEIM CORPORATION

Introduction

According to the requirements of 21 CFR 807.92, the following [redacted]ion 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 8240
Fax: (510) 687-1850
Contact Person: Yvette Lloyd

Date Prepared: March 6, 1997

2. Device name

Proprietary name: CEDIA® Digoxin Assay

Common name: Homogeneous enzyme immunoassay for the determination of Digoxin.

Classification name: Enzyme immunoassay, Digoxin

3. Predicate device

The Boehringer Mannheim CEDIA® 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).

Continued on next page

BOEHRINGER MANNHEIM CORPORATION

[redacted]

4. Device Description

The CEDIA® Digoxin Assay is based on the bacterial enzyme ß-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, digoxin in the sample competes with analyte conjugated to one inactive fragment of ß-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive ß-galactosidase fragments, and no active enzyme is formed.

Continued on next page

BOEHRINGER MANNHEIM CORPORATION

Intended use

Immunoassay for the in vitro quantitative determination of Digo[redacted]man serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim CEDIA® 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 CEDIA® 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: 0.15 - 4 ng/mL

Continued on next page

BOEHRINGER MANNHEIM CORPORATION

[redacted]

6. Comparison to predicate device cont.

Differences:

Feature	CEDIA® Digoxin	TDx Digoxin II
Reaction test principle	Spectrophotometric 570 nm	Fluorescence Polarization
Instrument required	Hitachi 911	Abbott TDx

Performance Characteristics:

Feature	CEDIA® Digoxin			TDx Digoxin II		
Precision	Modified NCCLS (ng/mL):			NCCLS (ng/mL):		
Level	Level 1	Level 2	Level 3	Low	Mid	High
N	120	120	120	50	50	50
Within run	1.0	1.7	3.8	0.70	1.44	3.66
%CV	4.25	3.45	1.45	5.75	3.15	1.87
Total	1.0	1.7	3.8	0.70	1.44	3.66
%CV	6.71	4.17	2.01	7.67	3.98	1.91

Continued on next page

BOEHRINGER MANNHEIM CORPORATION

Comparison to predicate device, (cont.)

Performance Characteristics:

[redacted]

Feature	CEDIA® Digoxin	TDx Digoxin II
Lower Detection Limit	0.15 ng/mL	0.2 ng/mL
Linearity	0.15 - 4 ng/mL	0.0 - 4.0 ng/mL
Method Comparison	Vs Abbott TDx Digoxin Least Squares y =0.97x - 0.17 r=0.9667 N=99 Deming's: y=1.00x - 0.22 r=0.9667 N=99	Vs Baxter Dade Stratus y =0.94x + 0.08 r=0.962 N=200

Continued on next page

BOEHRINGER MANNHEIM CORPORATION

Comparison to predicate device, (cont.)

Performance Characteristics:

[redacted]

Feature	CEDIA® Digoxin	TDx Digoxin II
Interfering substances	No interference at: (within ±~~10~~ 15% of baseline)	No interference at:
Bilirubin	66 mg/dL	20 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
~~Lipemia~~ Triglyceride	100 mg/dL	2500 mg/dL
Total Protein	10 g/dL	N/A
Rheumatoid Factor	100 IU/mL	N/A
Specificity	% Cross-reactivity	% Cross-reactivity
Digoxigenin	59.3	up to 200
β-Acetyldigoxin	71.3	not tested
α-Acetyldigoxin	67.5	not tested
Gitalin	3.7	not tested
Digoxingenin-Mono-Digitoxiside	100.5	
Digitoxin-Bis-Digitoxiside	77.3	up to 200
Digitoxin	17.6	up to 200
β-Methyldigoxin	71.3	4.8
3-Epe-Digoxigenin	37.5	not tested
3-Dehydrodigoxigenin	47.4	not tested
Epi-Digoxigenin-Glucuronide	40.5	not tested