K963840

NOV 20 1996

[redacted] Diagnostics

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

Contact Person: Yvette Lloyd

Date Prepared: September 20, 1996

2. Device name

Proprietary name: CEDIA® Phenytoin II Assay

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

Classification name: Enzyme immunoassay, Diphenylhydantoin

3. Predicate device

The Boehringer Mannheim CEDIA® Phenytoin II Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed CEDIA® Phenytoin Assay (K905689).

4. Device Description

The CEDIA® Phenytoin II 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, phenytoin 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.

---

5. Intended use

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

---

6. Comparison to predicate device

The Boehringer Mannheim CEDIA® Phenytoin II Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed CEDIA® Phenytoin Assay (K905689).

The following table compares the CEDIA® Phenytoin II Assay with the predicate device, CEDIA® Phenytoin 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 phenytoin
- Sample type: Serum and plasma
- Assay range: 0 - 40 µg/mL
- Same Antibody
- Same Conjugate

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device cont.

Differences:

Feature	CEDIA® Phenytoin II	CEDIA® Phenytoin
Reaction test principle	Spectrophotometric 570 nm	Spectrophotometric 415 nm
Instrument required	Hitachi 911	Hitachi 704
Enzyme Substrate	CPRG (Chlorophenol red-β-D-Galactopyranoside)	m-CNPG (m-Cyano-p-nitrophenol-β-D-galactopyranoside)

Performance Characteristics:

Feature	CEDIA® Phenytoin II			CEDIA® Phenytoin		
Precision	Modified NCCLS (µg/mL):			Modified NCCLS (µg/mL):		
Level	Sample	Control 2	Control 3	Low	Mid	High
N	120	120	120	120	120	119
Within-Run	6.30	14.80	26.75	10.7	17.7	35.4
%CV	3.2	2.0	1.3	3.6	2.0	1.5
Total	6.30	14.80	26.75	10.7	17.7	35.4
%CV	5.1	3.1	2.3	4.7	3.8	3.3

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® Phenytoin II	TDx Phenytoin
Lower Detection Limit	0.6 µg/mL	0.6 µg/mL
Linearity	0.6 - 40.0 µg/mL	0.6 - 40.0 µg/mL
Method Comparison	Vs CEDIA® Phenytoin Least Squares y =1.00x - 0.17 r=0.998 SEE =0.55 N=114 Deming's y =1.00x - 0.19 r=0.998 SEE =0.39 N=114	Vs Abbott TDx® Phenytoin Least Squares y =0.984x - 0.10 r=0.994 N=92

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® Phenytoin II	CEDIA Phenytoin
Interfering substances	No interference at:	No interference at:
Bilirubin	66 mg/dL	50 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Lipemia	1000 mg/dL	1000 mg/dL
Total Protein	12.0 g/dL	13 g/dL
Rheumatoid Factor	100 IU/mL	180 IU/mL
Specificity	% Cross-reactivity	% Cross-reactivity
HPPH	1.8%	1.4%
5-MPPH	5.7%	4.8%