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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.

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2. Device name Proprietary name: CEDIA® Procainamide Assay
Common name: Homogeneous enzyme immunoassay for the determination of procainamide.
Classification name: Enzyme immunoassay, procainamide

3. Predicate device The Boehringer Mannheim CEDIA® Procainamide 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® Procainamide Assay (K834464).

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510(k) Summary, Continued

**4.
Device
Description**

The CEDIA[®] Procainamide Assay is based on the bacterial enzyme β -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, procainamide in the sample competes with analyte conjugated to one inactive fragment of β -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 β -galactosidase fragments, and no active enzyme is formed.

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510(k) Summary, Continued

5. Intended use Immunoassay for the in vitro quantitative determination of procainamide in human serum and plasma.

6. Comparison to predicate device The Boehringer Mannheim CEDIA® Procainamide 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® Procainamide Assay (K834464).

The following table compares the CEDIA® Procainamide Assay with the predicate device, Abbott TDx® Procainamide 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 procainamide
- Sample type: Serum and plasma
- Assay range: 0-⁴20 µg/mL

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6.
Comparison
to predicate
device cont.

Differences:

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

Performance Characteristics:

Feature	CEDIA® Procainamide			TDx Procainamide		
Precision	Modified NCCLS (µg/mL)			Modified NCCLS (µg/mL):		
Level	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
N	120	120	120	80	80	80
Within-Run %CV	2.6	6.2	10.8	2.07	6.92	15.13
Total %CV	1.7	1.7	1.4	2.5	1.9	2.2
Total %CV	2.6	6.2	10.8	2.07	6.92	15.13
%CV	3.1	3.0	2.8	5.4	4.2	4.6

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® Procainamide	TDx Procainamide
Lower Detection Limit	0.4 µg/dL	0.1 µg/dL
Linearity	0.4 - 20 µg/dL (with a deviation from a linear line of ±10%)	0.0 - 20.0 µg/dL
Method Comparison	Vs Abbott TDx Procainamide <u>Least Squares</u> $y = 1.04x + 0.03$ $r = 0.9914$ $SEE = 0.42$ $N = 122$ <u>Deming's:</u> $y = 1.04x - 0.01$ $r = 0.9914$ $SEE = 0.30$ $N = 122$	Vs Enzyme Immunoassay Procainamide <u>Least Squares</u> $y = 1.01x - 0.18$ $r = 0.990$ $N = 262$

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® Procainamide	TDx Procainamide
Interfering substances	No interference at:	No interference at:
Bilirubin	66 mg/dL	15 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Lipemia	1000 mg/dL	1200 mg/dL
Protein	6.5 g/dL Albumin 10 g/dL IgG	9.5 mg/dL
Rheumatoid Factor	66 IU/ml	N/A
Specificity	% Cross-reactivity	% Cross-reactivity
N-Acetyl-procainamide	1.0	1.0
Desethyl-N-Acetyl-procainamide	0.1	None Detected
Desethyl procainamide	16.3	15
Procaine HCl	1.7	N/A

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