K963306

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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

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2. Device name

Proprietary name: CEDIA® N-acetylprocainamide Assay

Common name: Homogeneous enzyme immunoassay for the determination of N-acetylprocainamide.

Classification name: Enzyme immunoassay, N-acetylprocainamide

3. Predicate device

The Boehringer Mannheim CEDIA® N-acetylprocainamide 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® N-acetylprocainamide Assay (K830206).

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4. Device Description

The CEDIA® N-acetylprocainamide 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, N-acetylprocainamide 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.

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5. Intended use	Immunoassay for the in vitro quantitative determination of N-acetylprocainamide in human serum and plasma.
6. Comparison to predicate device	The Boehringer Mannheim CEDIA® N-acetylprocainamide 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® N-acetylprocainamide Assay (K830206). The following table compares the CEDIA® N-acetylprocainamide Assay with the predicate device, Abbott TDx® N-acetylprocainamide 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 N-acetylprocainamide •Sample type: Serum and plasma •Assay range: 0.6 - 30 µg/mL

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6. Comparison to predicate device cont.

Differences:

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

Performance Characteristics:

Feature	CEDIA® N-acetylprocainamide			TDx N-acetylprocainamide		
Precision	Modified NCCLS (µg/mL):			NCCLS (µg/mL):		
Level	Level 1	Level 2	Level 3	Low	Mid	High
N	120	120	120	120	120	120
Within run mean	1.91	4.41	10.75	4.06	9.18	23.80
%CV	5.84	3.35	2.29	3.3	1.7	2.3
Total mean	1.91	4.41	10.75	4.06	9.18	23.80
%CV	7.35	4.08	2.87	3.1	2.4	5.5

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® N-acetylprocainamide	TDx N-acetylprocainamide
Lower Detection Limit	0.6 µg/dL	0.6 µg/dL
Linearity	0.6 - 30 µg/dL	0.0 - 30.0 µg/dL
Method Comparison	Vs Abbott TDx N-acetylprocainamide Least Squares y =1.04x + 0.21 r=0.994 N=125 Deming's: y=1.04x + 0.18 r=0.9940 N=125	Vs Enzyme Immunoassay N-acetylprocainamide y =1.06x - 0.60 r=0.986 N=96

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	CEDIA® N-acetylprocainamide	TDx N-acetylprocainamide
Interfering substances	No interference at: (±10% of error)	No interference at:
Bilirubin	66 mg/dL	15 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Lipemia	1200 mg/dL	1200 mg/dL
Total Protein	13 g/dL	9.5 mg/dL
Rheumatoid Factor	85 IU/mL	N/A
Specificity	% Cross-reactivity	% Cross-reactivity
Procainamide	0.1	None detected
Desethyl-N-Acetyl-procainamide	21.7	18.2
Desethyl-procainamide	0.1	Not tested