K962734

DEC 10 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

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Date Prepared: July 11, 1996

2) Device name

Proprietary name: CEDIA DAU Benzodiazepine Assay

Common name: Homonogeneous enzyme immunoassay for the determination of benzodiazepine levels in urine.

Classification name: Benzodiazepine test system

3) Predicate device

We claim substantial equivalence to the CEDIA DAU Benzodiazepine Assay (K954626)

Continued on next page

510(k) Summary, Continued

4) Device Description

The modified CEDIA® DAU Benzodiazepine Assay is an in-vitro homogeneous enzyme immunoassay used for the qualitative and semiquantitative measurement of benzodiazepines in urine. It is based on competitive binding concepts employing benzodiazepine derivative labeled enzymatic fragments (ß-galactosidase) competing with sample benzodiazepines for the benzodiazepine-specific antibody.
Using recombinant DNA techniques, the ß-galactosidase molecule has been split into two totally inactive polypeptide subunits called enzyme acceptor and enzyme donor. A benzodiazepine derivative has been covalently linked to the enzyme donor in a manner that does not prevent spontaneous reassociation of the subunits to yield active ß-galactosidase enzyme. Benzodiazepine-specific antibody, by binding to the benzodiazepine derivative on the enzyme donor will inhibit enzyme reassociation, thereby regulating the level of ß-galactosidase formed. The amount of enzyme formed is proportional to the amount of benzodiazepines as monitored by the hydrolysis of the substrate chlorophenol red-ß-D-galactopyranoside (CPRG).

The optional b-Glucuronidase reagent, when added to the Enzyme Acceptor reagent and mixed with sample on the analyzer, hydrolyzes glucuronide metaboliotes of benzodiazepines, thereby increasing the recognition of samples containing benzodiazepine metabolites.

5) Intended use

The Modified CEDIA DAU Benzodiazepine Assay is a homogeneous enzyme immunoassay for the qualitative and semi-quantitative assay of benzodiazepines in human urine. Measurements are used as an aid in the diagnosis and treatment of benzodiazepine use or overdose.

Continued on next page

510(k) Summary, Continued

6) Comparison to predicate device

The Boehringer Mannheim modified CEDIA DAU Benzodiazepine Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Boehringer Mannheim CEDIA DAU Benzodiazepine Assay (K954626).

The following table compares the modified CEDIA DAU Benzodiazepine Assay with the predicate device, CEDIA DAU Benzodiazepine 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:

- Both Assays use the same kit
- Both assays are used on the BM/Hitachi 717 analyzer using the same chemistry parameters
- Both assays are for qualitative and semiquantitative determination of benzodiazepines in urine.

Differences:

- Addition of ß-Glucuronidase to the reconstituted Enzyme Acceptor reagent. (This component is sold separately.)
- Higher sensitivity to conjugated benzodiazepine compounds
- When ß-Glucuronidase is utilized, only the 200 ng/mL cutoff is available.

Continued on next page

510(k) Summary, Continued

6) Comparison to predicate device, (cont.)

Performance Characteristics: (note: data generated from modified CEDIA DAU Benzodiazepine assay used the β-Glucuronidase application.)

Feature	Modified CEDIA DAU Benzodiazepine			CEDIA DAU Benzodiazepine		
Precision	Modified NCCLS (mA/min): 200 ng/mL Cutoff Protocol			Modified NCCLS (mA/min): 200 ng/mL Cutoff Protocol		
Concentration Level	150	200	250	150	200	250
N	120	120	120	120	120	120
Within-Run	303.0	331.7	363.1	299.6	324.3	362.1
%CV	0.8	0.8	0.9	0.9	0.8	0.9
Total	303.0	331.7	363.1	299.6	324.3	362.1
%CV	5.9	6.0	5.8	3.5	3.5	3.5
Sensitivity (LOD) 200 ng/mL Cutoff	12.3 ng/mL			10.8 ng/mL		
Sensitivity (LOQ) 200 ng/mL Cutoff	12.1 ng/mL			10.7 ng/mL		
Accuracy	Vs. CEDIA Benzodiazepine Assay			Vs. EMIT II Benzodiazepine Assay		
200 ng/mL Cutoff						
Sensitivity	100.0%			98.2%		
Specificity	95.1%			99.1%		

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510(k) Summary, Continued

Comparison to predicate device (cont.)

Feature	Modified CEDIA DAU Benzodiazepine	CEDIA DAU Benzodiazepine
Interfering substances	Less than 10% error at:	Less than 10% error at:
Acetone	1 g/dL	1 g/dL
Ascorbic Acid	0.15 g/dL	0.15 g/dL
Creatinine	0.5 g/dL	0.5 g/dL
Ethanol	1 g/dL	1 g/dL
Galactose	10 mg/dL	10 mg/dL
γ-globulin	0.5 g/dL	0.3 g/dL
Glucose	3 g/dL	1.5 g/dL
Hemoglobin	0.3 g/dL	0.3 g/dL
Human Serum Albumin	0.5 g/L	0.5 g/L
Oxalic Acid	0.1g/dL	0.1g/dL
Riboflavin	7.5 mg/dL	7.5 mg/dL
Sodium Chloride	6 g/dL	6 g/dL
Urea	4 g/dL	6 g/dL
Specificity	Multiple benzodiazepine compounds	Multiple benzodiazepine compounds