

K962795

OCT 30 1996

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
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Date Prepared: September 18, 1996

2) Device name Proprietary name: CEDIA DAU Opiate 2K Assay

Common name: Homogeneous enzyme immunoassay for the determination of opiate levels in urine.

Classification name: Opiate test system

3) Predicate device We claim substantial equivalence to the CEDIA DAU Opiate Assay (K935346).

4) Device Description The CEDIA® DAU Opiate 2K Assay is an in-vitro homogeneous enzyme immunoassay used for the qualitative measurement of opiates in urine. It is based on competitive binding concepts employing morphine derivative labeled enzymatic fragments (β -galactosidase) competing with sample morphine for the morphine-specific antibody.

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510(k) Summary, Continued

4) Device Description, cont.

Using recombinant DNA techniques, the β -galactosidase molecule has been split into two totally inactive polypeptide subunits called enzyme acceptor and enzyme donor. Morphine has been covalently linked to the enzyme donor in a manner that does not prevent spontaneous reassociation of the subunits to yield active β -galactosidase enzyme. Morphine-specific antibody, by binding to the morphine on the enzyme donor will inhibit enzyme reassociation, thereby regulating the level of β -galactosidase formed. The amount of enzyme formed is proportional to the amount of opiates as monitored by the hydrolysis of the substrate chlorophenol red- β -D-galactopyranoside (CPRG).

5) Intended use

The CEDIA DAU Opiate 2K Assay is a homogeneous enzyme immunoassay for the qualitative assay of opiates in human urine. Measurements are used in the diagnosis and treatment of opiate use or overdose.

6) Comparison to predicate device

The Boehringer Mannheim CEDIA DAU Opiate 2K 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 Opiate Assay.

The following table compares the CEDIA DAU Opiate 2K Assay with the predicate device, CEDIA DAU Opiate 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 CEDIA DAU Enzyme Acceptor, Enzyme Donor and Enzyme Donor Buffer components.
 - Both assays utilize the same antibody
 - Both assays are used on the BM/Hitachi 717 analyzer using the same chemistry parameters.
 - Both assays are for the determination of opiates in urine.
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510(k) Summary, Continued

6)
Comparison
to predicate
device, cont.

Differences:

Feature	CEDIA DAU Opiate 2K	CEDIA DAU Opiate
Cutoff Level	2000 ng/mL	300 ng/mL
Antibody Concentration	13 µg/mL	3 µg/mL
Intended Use	Qualitative	Qualitative and semiquantitative

Performance Characteristics:

Feature	CEDIA DAU Opiate 2K			CEDIA DAU Opiate		
Precision	Modified NCCLS (mA/min):			Modified NCCLS (mA/min):		
Concentration Level	<u>1500</u>	<u>2000</u>	<u>2500</u>	<u>225</u>	<u>300</u>	<u>375</u>
N	120	120	120	120	120	120
Within-Run %CV	240.1	296.8	353.8	269.8	316.8	361.4
Total %CV	1.3	1.4	1.3	1.6	1.4	1.3
Total %CV	240.1	296.8	353.8	269.8	316.8	361.4
	4.6	5.0	4.4	4.2	4.8	4.2
Sensitivity (LOD)	60.9 ng/mL			21.6 ng/mL		
Accuracy Relative Sensitivity	70.6% of CEDIA DAU Opiate			100% of Emit® II		
Accuracy Relative Specificity	100% of CEDIA DAU Opiate			100% of Emit® II		

Interfering substances	Less than 10 % error in drug detection at:	Less than 10 % error in drug detection at:
Glucose=	3 g/dL	3 g/dL
Sodium Chloride=	6 g/dL	6 g/dL
Protein=	0.5 g/dL	0.5 g/dL
Urea=	5 g/dL	6 g/dL

Feature	CEDIA DAU Opiate 2K	CEDIA DAU Opiate
Specificity	Major Detectables: Morphine Morphine-3-glucuronide Codeine Hydrocodone Hydromorphone 6 Monoacetylmorphine	Major Detectables: Morphine Morphine-3-glucuronide Codeine Hydrocodone Hydromorphone 6 Monoacetylmorphine