K965157

Jan. 17, 1997

[redacted]) Summary

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CORPORATION

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: December 20, 1996

2. Device name

Proprietary name: Multi-Drug Control Set, Speciality Control Set 1

Common name: Liquid Drugs of Abuse Controls

Classification name: Quality Control material (unassayed), Urinalysis Controls (unassayed)

3. Predicate device

The Boehringer Mannheim modified Multi-Drug Control Set is substantially equivalent to the Medical Analysis Systems (MAS) Liquid Urinalysis Controls (K935062). The Boehringer Mannheim modified Specialty Control Set 1 is substantially equivalent to the Multi-Drug Control Set (K951135).

4. Device Description

The Multi-Drug Control Set and the Specialty Control Set 1 are manufactured using human urine, multiple drugs of abuse, stabilizers, and preservatives. The drugs are appropriately spiked into the control matrix to the correct control concentration levels. The controls are in process checked and quality controlled against in-house reference calibrators (prepared using a similar procedure) which have been value assigned by CEDIA.

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510(k) Summary, Continued

5. Intended use

The modified Multi-Drug Specialty Control Set and the modified Specialty Control Set 1 are intended to be used as quality control material to monitor drugs of abuse assays.

6. Substantial equivalence

The Boehringer Mannheim modified Multi-Drug Control Set and the modified Specialty Control Set 1 are modifications of existing products.

The Boehringer Mannheim modified Multi-Drug Control Set is substantially equivalent to the Medical Analysis Systems (MAS) Liquid Urinalysis Controls (K935062). The Boehringer Mannheim modified Specialty Control Set 1 is substantially equivalent to the Multi-Drug Control Set (K951135).

The following tables compare the modified Multi-Drug Control Set and the modified Specialty Control Set 1 with the respective predicate devices, Specialty Control Set 1 and the MAS Liquid urinalysis Controls. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in provided in attachment 6.

Similarities: Multi-Drug Control and MAS Liquid Urinalysis Controls

- Same matrix.
- Same composistion
- Same manufacturer.
- Same confirmatory method
- Same open vial stability claim

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6. Substantial equivalence, continued

Differences:

Feature	Modified Multi-Drug Control Set		MAS Liquid Urinalysis Controls		
Control Target Concentrations:	Control Level, ng/mL		Control Level, ng/mL		
	Low	High	2	3	4
LSD	0.3	0.7	0.3	0.7	4.0
Benzoylecgonine	225	375	225	360	500
d-Methamphetamine	750	1250	750	1200	2000
Methadone	225	375	225	360	750
Methaqualone	225	375	225	360	750
Morphine	225	375	225	360	750
Nitrazepam	225	375	n/a		
Phencyclidine	19	31	20	30	200
Propoxyphene	225	375	225	360	750
Secobarbital	225	375	150	250	1000
Intended Use	Monitoring assays for drugs of abuse.		Multi-analyte Drugs of Abuse Controls are intended for use as a consistent test sample of known concentration for monitoring assay conditions in a quantitative and qualitative analyses of patient urine specimens for drugs and drug metabolites.		

Performance Characteristics:

- Dose verification: Confirmation of target doses by GC/MS.
- Open Vial Stability Study: Equivalent performance as the predicate device

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6. Substantial Equivalence, continued

Similarities: Specialty Control Set 1 and Multi-Drug Control Set

- Same matrix.
- Same composistion
- Same manufacturer
- Same confirmatory method
- Same open vial stability claim

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Differences, continued:

Feature	Modified Specialty Control Set 1		Multi-Drug Control Set	
Control Target Concentrations:	Control Level, ng/mL		Control Level, ng/mL	
	Low	High	Low	High
Benzoylecgonine	112	188	225	375
Morphine	1500	2500	225	375
Methamphetamine	375	625	750	1250
Nitrazepam	150	250	225	375
Secobarbital	150	250	225	375
Intended Use	Monitoring assays for drugs of abuse.		The Multi-Drug Control Set is used as unassayed control material with drugs of abuse assays for amphetamines, barbiturates, benzodiazepines, cocaine metabolite, methadone, methaqualone, opiates, phencyclidine, and propoxyphene.	

Performance Characteristics:

- Dose verification: Confirmation of target doses by GC/MS.
- Open Vial Stability Study: Equivalent performance as the predicate device