510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k101752

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Benzoylecgonine, Morphine, Phencyclidine

D. Type of Test:

Calibrator materials

E. Applicant:

Microgenics Corporation

F. Proprietary and Established Names:

Thermo Scientific CEDIA® Multi-Drug OFT Calibrators

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKB	Class II	21 CFR§ 862.3200	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The CEDIA® Multi-Drug OFT Calibrators are intended for use in the calibration of d-Amphetamine, Benzoylecgonine, Morphine, and Phencyclidine (PCP) in

human Oral Fluid when used with the CEDIA Amphetamine, Cocaine, Opiate, and Phencyclidine (PCP) OFT Assays on the MGC 240 analyzer. This in vitro diagnostic device is intended for clinical laboratory use only.

3. Special conditions for use statement(s):

   For in vitro diagnostic use

   For prescription use

4. Special instrument requirements:

   For use with CEDIA® Amphetamine, Cocaine, Opiate, and Phencyclidine (PCP) OFT Assays on the MGC240 analyzer

I. Device Description:

The CEDIA® Multi-Drug OFT Calibrators are liquid ready-to-use solutions prepared by spiking known quantities of Amphetamine, Benzoylecgonine, Morphine, and PCP into buffer matrix. The CEDIA® Multi-Drug OFT Calibrators consists of 3 calibrator levels: Negative Calibrator, Cutoff Calibrator, and High Calibrator. The Cutoff Calibrator is used as a qualitative cutoff reference for distinguishing "positive" from "negative" samples. The volume per vial is 20.0 mL for the Negative Calibrator and 10.0 mL for the Cutoff and High Calibrator. Amphetamine, Benzoylecgonine, Morphine, and PCP are value assigned for use with CEDIA® OFT Assays. The Negative Calibrator is free of analyte.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CEDIA® DAU Multi-Drug Calibrators

2. Predicate 510(k) number(s):

   k980853

3. Comparison with predicate:

Similarities

Item	Candidate Device	Predicate Device
Intended Use	The CEDIA® Multi-Drug OFT Calibrators are intended for use in the calibration of CEDIA® OFT Assays.	Same

Form	Liquid, ready to use	Same
Storage temperature	2 to 8° C	Same

Differences

Item	Candidate Device	Predicate Device
Analytes	Amphetamine, Benzolyecgonine, Morphine, Phencyclidine	Benzolecgonine, EDDP, d-Methamphetamine, Morphine, Nitrazepam, Phencyclidine, Secobarbital
Matrix	Buffer	Urine
Calibrator Levels	3 Levels – Negative, Cutoff, High	4 Levels – Primary, Secondary, Intermediate, High
Stability	Shelf Life – 16 months Open Vial – 60 days	Until indicated expiration date

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

The sponsor claims traceability to all measurands in the calibrator (amphetamine, benzoylecgonine, morphine, phencyclidine) to a commercially available methanolic standard.

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the CEDIA® Multi-Drug OFT Calibrators were determined using accelerated and real time closed (un-opened) vial, as well as real-time opened vial studies. A closed vial shelf-life of 16 months at the recommended storage temperature (2°C to 8°C) was demonstrated based on real-time studies. Open vial stability of 60 days was also demonstrated at the recommended storage temperature (2°C to 8°C). The closed vial shelf-life and open vial expiration dates are listed on the box and vial labels. In the package insert, the user is directed to check the expiration dates indicated on the box label. The recommendations in the labeling are to store calibrators at 2°C to 8°C.

Value Assignment and Validation

Nominal values are assigned to production lots using Liquid Chromatography with tandem Mass Spectrometry (LC-MS/MS). The table below shows the measurand values contained in each level of calibrator materials. These values are also provided in the labeling.

Analyte	Negative Calibrator (ng/mL)	Cutoff Calibrator (ng/mL)	High Calibrator (ng/mL)
Amphetamine	0.0	50.0	200.0
Benzoylecgonine	0.0	5.0	50.0
Morphine	0.0	10.0	80.0
Phencyclidine	0.0	1.0	20.0

Three lots of each level of calibrator was validated using the CEDIA® Multi-Drug OFT Assays, a reference set of calibrators, and two MGC 240 Benchtop Clinical Chemistry Analyzers set to qualitative mode. The validation protocol, acceptance criteria, and data were reviewed and found to be acceptable.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The values for each analyte are stated in the labeling

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.