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

A. 510(k) Number:

k103656

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for d-methamphetamine, secobarbital, nitrazepam, oxazepam, buprenorphine, benzoylecgonine, cotinine, ethyl glucuronide, ethanol, LSD, methadone, EDDP, methaqualone, morphine, oxycodone, phencyclidine, propoxyphene, nortriptyline, and L- Δ^9-THC-COOH.

D. Type of Test:

Not applicable

E. Applicant:

Microgenics Corporation

F. Proprietary and Established Names:

Thermo Scientific MAS® DOA Total

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIF	Class I, reserved	21 CFR 862.3280	Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use

2. Indication(s) for use:

MAS® DOA Total is intended for use as an assayed control for monitoring assay conditions in semi-quantitative and qualitative analysis of patient urine specimens for drugs and drug metabolites. These controls are human urine based and are composed of d-methamphetamine, secobarbital, nitrazepam, oxazepam, buprenorphine, benzoylecgonine, cotinine, ethyl glucuronide, ethanol, LSD, methadone, EDDP, methaqualone, morphine, oxycodone, phencyclidine, propoxyphene, nortriptyline, and L- Δ^9-THC-COOH.

MAS® DOA Total provides an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects.

3. Special conditions for use statement(s):

DOA TOTAL offers levels of controls, at concentrations 25% below and 25% above the screening cutoff levels for D-methamphetamine, PCP (Phencyclidine), Opiates, Cocaine and Marijuana (Cannabinoid).

4. Special instrument requirements:

Validation studies were conducted using the following methods:

1) GC/MS assays are used for D-methamphetamine, Barbiturate, Nitrazepam, Oxazepam, Buprenorphine, Cocaine, Cotinine, Methadone, EDDP, Methaqualone, Opiates, Oxycodone, PCP, PPX, and THC.

2) LC/MS assays are used for ETG, LSD, and Nortriptyline.

3) EMIT Plus II assay is used for Ethanol.

I. Device Description:

Device Description
DOA TOTAL is prepared from confirmed drug free human urine pools. Each pool has been tested using FDA accepted methods and found to be non-reactive for HBsAg, Hepatitis C Antibody (HCV), and HIV-1 and HIV-2 antibody. Analyte levels are adjusted with purified drugs or drug metabolites. Preservatives and stabilizers are added to maintain product integrity.

The DOA Total Liquid Assayed Drugs of Abuse Controls are available by Level, or as a Multi-Pack.

Catalog Number	Description	Size
DOAT-1	Level1 Negative	6 vials of Level 1, 18 mL per vial

DOAT-2	Level 2	6 vials of Level 2, 18 mL per vial
DOAT-3	Level 3	6 vials of Level 3, 18 mL per vial
DOAT-4	Level 4	6 vials of Level 4, 18 mL per vial
DOAT-5	Level 5	6 vials of Level 5, 18 mL per vial
DOAT-6	Level 6	6 vials of Level 6, 18 mL per vial
DOAT-MP	Multi-pack	1 vial of Level 1, 18 mL per vial 1 vial of Level 2, 18 mL per vial 1 vial of Level 3, 18 mL per vial 1 vial of Level 4, 18 mL per vial 1 vial of Level 5, 18 mL per vial 1 vial of Level 6, 18 mL per vial

J. Substantial Equivalence Information:

1. Predicate device

Thermo Scientific MAS DOA-XSE

2. Predicate K number

K971058

3. Comparison of Technological Characteristics

Similarities and differences between new and predicate devices

Comparison	Subject Device	Predicate 1
Device	MAS DOA Total	MAS DOA-XSE (k971058)
Intended Use	MAS® DOA Total is intended for use as an assayed control for monitoring assay conditions in semi-quantitative and qualitative analysis of patient urine specimens for drugs and drug metabolites.	Same
Analytes by Configuration	DOA Total: d-Methamphetamine Benzoylecgonine EDDP	DOA XSE: d-Methamphetamine Benzoylecgonine -

	Ethanol LSD - Methadone Methaqualone Morphine Nitrazepam Oxazepam PCP Propoxyphene Secobarbital L-Δ^9-THC-COOH *Buprenorphine *Cotinine *EtG *Oxycodone *Nortriptyline -	Ethanol LSD - Methadone Methaqualone Morphine - Oxazepam PCP Propoxyphene Secobarbital L-Δ^9-THC-COOH - - - - -
Matrix	Urine Based	Same
Form	Liquid ready to use	Same
Control Levels	Level 1 Negative Level 2 Level 3 Level 4 Level 5 Level 6 Elevated High	Level 1 Negative Level 2 Low Level 3 High Level 4 Elevated High
Storage	2-8°C	2-8°C
Open Vial Stability	30 days	30 days
Shelf Life	24 months	24 months

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

None were referenced.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

Traceability:
The drug values in the DOA TOTAL control are determined by certified independent laboratories. With the exception of Ethanol, all analytes are tested by GC/MS or LC/MS. Ethanol was tested by EMIT Plus II assay, since there is no GC/MS or LC/MS method available currently. The assays are calibrated by reference standards that are traceable to National Institute of Standards and Technology (NIST).

Value Assignment:

The following procedure was used for value assignment

a. Assay Methodology used to assign values:
4) GC/MS assays are used for D-methamphetamine, Barbiturate, Nitrazepam, Oxazepam, Buprenorphine, Cocaine, Cotinine, Methadone, EDDP, Methaqualone, Opiates, Oxycodone, PCP, PPX, and THC.

5) LC/MS assays are used for ETG, LSD, and Nortriptyline.

6) EMIT Plus II assay is used for Ethanol.

b. Data Collection:
A minimum of 8 data points are collected for each assay. Data collected from at least two test sites, over at least two separate days in duplicates, are required.

c. Confirmation Value Range:

The sponsor assigned the following value assignment criteria

The high limits of L2 published ranges cannot exceed the 1st cutoff value, and the low limits of L3 published ranges cannot be lower than the 1st cutoff value.

The high limits of L4 published ranges cannot exceed the 2nd cutoff value, and the low limits of L5 published ranges cannot be lower than the 2nd cutoff value.

Stability

Open Vial (5°C) Stability

Three lots of assays containing all levels (3X Level 1-6 vials) were opened with 1 mL sample volume removed twice a week for a total of 30 days to simulate actual customers' usage. On day 31, these samples and their respective samples from unopened vials are assayed to evaluate the product open bottle stability.

Data support the 30-day open bottle stability at 5°C for all analytes in the three pilots evaluated.

Stress Stability to Predict 5°C Shelf Life

Two elevated temperatures at 41°C and 25°C were used to evaluate stress stability to predict control shelf life at 5°C.

Levels 1 to 6 were incubated at 41°C for 12 days and at 25°C for 90 days. Multiple time points were tested using the staggered start method, and the time to failure (TTF) is determined by linear regression.

Data support the acceptance criteria and hence the recommended 5°C shelf life claim of 24 months.

Summary table:

Evaluation Parameter	Acceptance Criteria	Specification	Pass / Fail
Open Bottle Stability at 5°C	30 days	L1: Negative L2-L6: recovery change within +/-10%	Pass
Close Bottle Stability – Product Shelf Life (5°C)	24 months (predicted)	L1: Negative L2-L5: recovery change within +/-15% L6: recovery change within +/-20%	Pass

Real-time Stability

Procedure:

Three lots of the assay containing all levels (Levels 1 to 6) controls were stored at 5°C on day zero. Real-time stability monitoring is in process. The

analyte concentrations of freshly opened vials have been assayed on days 0, 100, 170, 230, and 300 thus far, and studies will continue to establish the 5°C shelf life claim. The point of failure is determined by linear regression.

Real-time stability monitoring for all three lots will be continued to substantiate the above predicted claims.

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:

Analyte	L1	L2	L3	L4	L5	L6	Concentration
d-Methamphetamine	0	750	1250	375	625	2000	ng/mL
Secobarbital	0	225	375	150	250	1000	ng/mL
Nitrazepam	0	225	375	0	0	0	ng/mL
Oxazepam	0	0	0	150	250	1000	ng/mL
Buprenorphine	0	0	0	15	25	60	ng/mL
Benzoylecgonine	0	225	375	112	118	500	ng/mL
Cotinine	0	375	625	0	0	0	ng/mL
ETG	0	375	625	750	1250	0	ng/mL

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.