510K SUMMARY

MAR 2 4 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K103656

Company/Contact person

Lisa Charter
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Date Prepared

February 10, 2011

Regulatory Declarations

Common / Usual Name	MAS® DOA Total
Trade/ Proprietary Name	Thermo Scientific MAS® DOA Total
Classification Regulation	21 CFR 862.3280
Device Class	Class I
Device Regulation Panel	Toxicology
Product Code	DIF

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. 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.

Legally marketed device to which equivalency is claimed

MAS® DOA Total is substantially equivalent to the previously cleared MAS DOA-XSE (K971058) and MGC DAU Control Sets: Primary, Clinical, and Select (K040758).

Description of Device

DOA TOTAL is prepared from certified drug free human urine pools. Analyte levels are adjusted with purified drugs or drug metabolites. Preservatives and stabilizers are added to maintain product integrity.

DOA TOTAL offers levels of controls, at concentrations 25% below and 25% above the screening cutoff levels used by the United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA); for Amphetamines, PCP (Phencyclidine), Opiates, Cocaine and Marijuana (Cannabinoid).

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
Ethanol	0	15	25	40	70	300	mg/dL
LSD	0	0.3	0.7	0.3	0.7	2.5	ng/mL
Methadone	0	225	375	225	375	750	ng/mL
EDDP	0	75	125	750	1250	1500	ng/mL
Methaqualone	0	225	375	225	375	750	ng/mL
Morphine	0	225	375	1500	2500	750	ng/mL
Oxycodone	0	75	125	225	375	750	ng/mL
PCP	0	19	31	19	31	100	ng/mL
PPX	0	225	375	225	375	750	ng/mL
Nortriptyline	0	185	415	750	1250	0	ng/mL
L-Δ-9-THC-COOH	0	19	31	38	62	150	ng/mL

Summary of Clinical Testing

Evaluation Parameter	Acceptance Criteria	Specification	Pass / Fail
Target achievement	Analyte concentrations meet specification	L1: Negative L2 –L6: recovery difference vs. target within +/-10%, except LSD which is within +/-15%	Pass
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

Conclusion

As summarized, the MAS® DOA Total is substantially equivalent to previously cleared MAS DOA-XSE and MGC DAU Control Sets: Primary, Clinical, and Select. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 24 2011

Microgenics Corporation
Thermo Fisher Scientific, Clinical Diagnostics Division
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538-6406

Re: k103656
Trade Name: Thermo Scientific MAS R DOA Total
Regulation Number: 21 CFR §862.3280
Regulation Name: Clinical toxicology control material.
Regulatory Class: Class I, reserved
Product Codes: DIF
Dated: February 10, 2011
Received: February 14, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103656

Device Name: Thermo Scientific MAS® DOA Total

Indication for Use:

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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.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103656