MAY 2 8 2004

SECTION II

510(k) SUMMARY

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

510(k) Number: k040758

Submitter:
Microgenics Corporation
46360 Fremont Blvd
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Contact Person:

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Telephone: (510)-979-5012
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Preparation Date:

March 23, 2004

Device Information:

Device Classification Name:	Drug Mixture Control Materials
Device Description	Clinical toxicology control material
Proprietary Name:	MGC DAU Control Sets: Primary, Clinical and Select
Regulation Number:	21 CFR§862.3280
Product Code:	DIF
Regulatory Class:	Class I

Predicate Devices:

Evaluation of the data and results enclosed herein demonstrate that each configuration of the MGC DAU Control Sets is substantially equivalent in form and function to the Multi-Drug Control Set (K951135) for its stated intended use.

Device Description:

Each configuration of the MGC DAU Control Sets is prepared in a human urine matrix, with stabilizers and preservatives added. As is shown in the table below, the MGC DAU Control Set is offered in three configurations differing only in the concentration and number of analytes offered.

Configuration	Drug	Low (ng/mL)	High (ng/mL)
Primary	Benzoylecgonine	225	375
	EDDP	750	1250
	d-Methamphetamine	750	1250
	Methadone	225	375
	Methaqualone	225	375
	Opiates	1500	2500
	Benzodiazepenes	225	375
	Phencyclidine	19	31
	Propoxyphene	225	375
	Barbituates	225	375
Clinical	Benzoylecgonine	225	375
	EDDP	75	125
	d-Methamphetamine	375	625
	Methadone	225	375
	Methaqualone	225	375
	Opiates	225	375
	Benzodiazepenes	225	375
	Phencyclidine	19	31
	Propoxyphene	225	375
	Barbituates	225	375
Select	6-Acetylmorphine	7.5	12.5
	Benzoylecgonine	112.5	187.5
	LSD	0.3	0.7
	MDMA	375	625
	Benzodiazepenes	225	375

Intended Use:

The MGC DAU Control Set consists of unassayed controls intended for use in the validation of drug of abuse assays performed using human urine.

Comparison to Predicate Device(s):

The MGC DAU Control Set is substantially equivalent to the Multi-Drug Control Set (K951135), also manufactured by Microgenics and previously cleared by FDA, for its stated intended use.

Device Characteristics	Subject Device	Predicate Device (K951135)
Intended Use	The MGC DAU Control Set consists of unassayed controls intended for use in the validation of drug of abuse assays performed using human urine.	The Multi-Drug Controls are for use as unassayed control material with drugs of abuse assays.
Analytes (by configuration)	Primary: Benzoylecgonine, EDDP, d-Methamphetamine, Methadone, Methaqualone, Opiates[1], Benzodiazapenes[2], Phencyclidine, Propoxyphene, Barbituates[3] Clinical: Benzoylecgonine, EDDP, d-Methamphetamine, Methadone, Opiates[1], Benzodiazapenes[2], Phencyclidine, Propoxyphene, Barbituates[3] Select: 6-Acetylmorphine, Benzoylecgonine, LSD, MDMA, Benzodiazapenes[4]	Benzoylecgonine, EDDP, LSD, d-Methamphetamine, Methadone, Methaqualone, Opiates[1], Benzodiazapenes[4], Phencyclidine, Propoxyphene, Barbituates[3]
Matrix	Urine	Urine
Control Form	Liquid	Liquid
Control Levels	Two: Low and High	Two: Low and High
Storage	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label.

[1]Morphine [2]Oxazepam [3]Secobarbital [4]Nitrazepam

Summary:

The information provided in this pre-market notification demonstrates that each configuration of the MGC DAU Control Set is substantially equivalent in form and function to the Multi-Drug Control Set (K951135) for its stated intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate devices. The information supplied in

this pre-market notification provides reasonable assurance that each configuration of the MGC DAU Control Set is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 8 2004

David Casal, Ph.D
Vice-President, Clinical, Regulatory and Quality Affairs
Microgenics Corp.
46360 Fremont Blvd.
Fremont, CA 94538

Re: k040758
Trade/Device Name: MGC DAU Control Sets: Primary, Clinical and Select
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: March 23, 2004
Received: April 12, 2004

Dear Dr. Casal:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
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): K040758

Device name: MGC DAU Control Sets: Primary, Clinical and Select

Indications for Use:

The MGC DAU Control Set consists of controls intended for use in the validation of drug of abuse assays performed using human urine.

Prescription Use __X_____ AND/OR Over-the Counter Use_____
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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