AUG 2 7 2003

510(k) Summary

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.

510(k) Number: **K023617**

Applicant Information:

Date Prepared:	July 16, 2003
Applicant:	Microgenics Corporation 46360 Fremont Boulevard Fremont, CA 94538
Contact Person:	David C Casal, Ph.D. Vice-President, Clinical, Regulatory and Quality Affairs
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Device Information:

Classification/Name:	Clinical Toxicology Test System, Methadone Test System Class II per 21 CFR §862.3620, Product Code DJR
Trade Name:	DRI® Methadone Metabolite Enzyme Assay
Common Name:	Methadone Metabolite Assay

Legally Marketed Predicate Device:

The subject DRI® Methadone Metabolite Enzyme Assay is substantially equivalent to the previously cleared (K931780) predicate DRI® Methadone Metabolite Enzyme Assay cleared. The subject DRI® Methadone Metabolite Enzyme Assay is identical or similar to its predicate in terms of intended use, method principle, device components, risk to the patient, and clinical performance.

Device Description:

The subject device, the DRI® Methadone Metabolite Enzyme Assay, is a ready-to-use, liquid homogeneous enzyme immunoassay. The assay uses specific antibodies that detect EDDP in human urine without cross-reactivity to the parent drug, methadone. The assay is based on the competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH. The subject DRI® Methadone Metabolite Enzyme Assay utilizes a new monoclonal antibody and enzyme-conjugate, with increased reagent stability and calibrator

and control separations.

Intended Use:

The Methadone Metabolite Immunoassay is intended to be used for the qualitative and semi-quantitative determination of the presence of Methadone Metabolite (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine or EDDP) in human urine at cutoffs of 300 and 1000 ng/mL. The semi-quantitative range of the assay is 31-2000 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect methadone metabolite in human urine.

Comparison to Predicate Device:

The subject DRI® Methadone Metabolite Enzyme Assay is essentially identical and therefore substantially equivalent to the predicate device. A comparison of salient descriptive and performance characteristics for the devices amply demonstrates that the subject device is substantially equivalent to the predicate device in form and function.

Comparison of the **Predicate (K931780) and Subject (K023617) Methadone Metabolite Assays**

Device Name	**Predicate Methadone Metabolite Assay (K931780)**	**Subject Methadone Metabolite Assay**
Indications for Use	"This homogeneous methadone metabolite enzyme immunoassay is intended for the qualitative and semiquantitative determination of the methadone metabolite, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), in human urine."	The Methadone Metabolite Immunoassay is intended to be used for the qualitative and semi-quantitative determination of the presence of Methadone Metabolite (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine or EDDP) in human urine at cutoffs of 300 and 1000 ng/mL. The semi-quantitative range of the assay is 31-2000 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect methadone metabolite in human urine.
Method Principle	The assay is based on the competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme	The assay is based on the competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity

Device Name	Predicate Methadone Metabolite Assay (K931780)	Subject Methadone Metabolite Assay
	activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.	is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.
Components	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent
Risk to patient	In vitro device, positive results must be confirmed by GC/MS.	In vitro device, positive results must be confirmed by GC/MS.
Clinical Performance	Accuracy: %Agreement with a commercial EIA Assay was 100% (57 true positives, 54 true negatives). Total Imprecision: Percent rate CVs across 4 levels of analyte concentration (0 ng/mL, 300 ng/mL, 1000 ng/mL, 2000 ng/mL) were ≤ 0.8%.	Accuracy: %Agreement with GC/MS was 95% (69 true positives, 73 true negatives). Total Imprecision: Percent rate CVs across 6 levels of analyte concentration (150 ng/mL, 300 ng/mL, and 500 ng/mL, 750 ng/mL, 1000 ng/mL, and 1250 ng/mL) were ≤ 0.9%. In dose mode, the %CV ≤ 5.7%

Summary of Non-Clinical and Clinical Data:

Performance characteristics for the subject DRI® Methadone Metabolite Enzyme Assay, including sensitivity, reproducibility, linearity, and clinical accuracy, were established in a series of laboratory and clinical studies. These studies demonstrated that the assay sensitivity is approximately 31 ng/mL, intra- and inter-assay reproducibility across the dynamic range of the assay is less than or equal to 5.7%, and that the assay is linear up to 2000 ng/mL. Additional studies also showed that there was adequate separation offered for specimens between 150 and 500 ng/mL using the 300 ng/mL control (cutoff) and between 750 and 1250 ng/mL for the 1000 ng/mL control (cutoff).

Method comparison studies show that methadone metabolite concentrations obtained using the subject DRI® Methadone Metabolite Enzyme Assay and the GC/MS reference method are 95% concordant. Specificity testing demonstrated that the DRI® Methadone Metabolite Enzyme Assay does not cross-react with methadone nor is the assay result deleteriously by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

Summary:

Based upon the product performance characteristics, intended use, and technical information provided in this premarket notification, the DRI® Methadone Metabolite Enzyme Assay has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Lakshmi Anne, Ph.D.
Director, Product Development
Microgenics Corporation
46360 Fremont Boulevard
Fremont, California 94538

AUG 27 2003

Re: k023617
Trade/Device Name: DRI® Methadone Metabolite Enzyme Assay
Regulation Number: 21 CFR § 862.3620
Regulation Name: Methadone Test System
Regulatory Class: II
Product Code: DJR, DLJ, LAS
Dated: May 29, 2003
Received: May 30, 2003

Dear Dr. Anne:

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.

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). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023617

Device name: DRI® Methadone Metabolite Enzyme Assay

Indications for Use:

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Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____

(per 21 CFR §801.109 (Optional Format 1-2-96)