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510K 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

The assigned 510(k) number is: K081378

COMPANY/CONTACT PERSON

Thermo Fisher Scientific
Microgenics Corporation
46360 Fremont Blvd.
Fremont, CA 94538

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JAN 14 2009

DATE PREPARED

December 3, 2008

DEVICE NAME

Trade Name:	DRI® Methadone Metabolite (100/300) Assay
	DRI® Methadone Metabolite Urine Calibrators
	DRI® Methadone Metabolite Urine Controls
Common Name:	Methadone Test System
Device Classification:	21 CFR 862.3620 Methadone Test System; Class II
	21 CFR 862.3200 Clinical Toxicology Calibrator; Class II
	21 CFR 862.3280 Clinical Toxicology Control Material; Class I

INTENDED USE

The DRI Methadone Metabolite (100/300) Assay is intended 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 100 and 300 ng/mL.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography / Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. Tests for methadone metabolite cannot distinguish between abused drugs and certain prescribed medications. Certain foods or medications may interfere with test for methadone metabolite and cause false positive results.

The DRI Methadone Metabolite Calibrators are intended for use in calibration of the DRI Methadone Metabolite (100/300) Assay.

The DRI Methadone Metabolite Controls are intended for use in the DRI Methadone Metabolite (100/300) Assay to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

The DRI Methadone Metabolite (100/300) Assay is substantially equivalent to the previously cleared CEDIA DAU EDDP Assay (K980746, Microgenics Corporation).

The DRI Methadone Metabolite Calibrators are substantially equivalent to the previously cleared CEDIA DAU Multi-Drug Calibrators (K980853, Microgenics Corporation).

The DRI Methadone Metabolite Controls are substantially equivalent to the previously cleared MGC DAU Control Sets: Primary, Clinical, Select (K040758, Microgenics Corporation).

DESCRIPTION OF DEVICE

The DRI Methadone Metabolite (100/300) Assay utilizes liquid ready-to-use reagents. The Antibody/Substrate Reagent (R1) contains mouse monoclonal anti-EDDP antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative. The Enzyme Conjugate Reagent (R2) contains EDDP-derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

The assay uses specific antibodies that can detect EDDP in human urine without cross-reactivity to the parent drug methadone. The assay is based on competition between drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) and free drug from the sample for a fixed number of specific antibody binding sites. In the presence of free drug from the sample, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. 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 enzyme activity. This enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	DRI Methadone Metabolite (100/300) Assay	Predicate Device – CEDIA DAU EDDP Assay
Intended Use	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 100 and 300 ng/mL.	Qualitative and semi-quantitative assay of EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine or EDDP) in human urine.
Test Principle	Homogeneous Enzyme Immunoassay based on 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. Direct relationship between drug concentration in urine and enzyme activity. Enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.	Homogeneous Enzyme Immunoassay based on competition between a drug labeled with ß-galactosidase, and free drug from the urine sample for a fixed amount of specific antibody binding sites. Direct relationship between drug concentration in urine and enzyme activity. Enzyme activity is determined spectrophotometrically at 570 nm by measuring its ability to convert CPRG to CPR.
Cutoff	100 and 300 ng/mL	100 ng/mL
Matrix	Human urine	Human urine
Reagents	Liquid Ready-to-Use Two reagent assay (R1 and R2)	Lyophilized (reconstitution required) Two reagent assay (R1 and R2)
Calibrators	Liquid ready-to-use (0, 100, 300, 500, 1000 ng/mL)	Liquid ready-to-use (0, 100, 500, 2000 ng/mL)
Controls	Liquid ready-to-use (± 25% from cutoffs)	Liquid ready-to-use (± 25% from cutoffs)

SUMMARY OF CLINICAL TESTING

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Sensitivity

Sensitivity measured semi-quantitatively as limit of quantitation (LOQ) was 14 ng/mL.

Precision

A precision study was performed using the CLSI guideline *EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition*

For qualitative mode, acceptance criteria required that all samples spiked at levels below the cutoff read as negative and all samples spiked at levels above the cutoff read as positive.

For semi-quantitative mode, target within-run precision was less than or equal to 8% CV and target total-run precision was less than or equal to 10% CV.

The within-run and total-run precision at all levels of the 100 cutoff and the 300 cutoff met target specifications in both qualitative and semi-quantitative modes.

Cutoff Characterization – Spike Recovery

In qualitative mode, the control levels were recovered accurately, with the negative controls recovering less than the cutoff calibrators and the positive controls recovering greater than the cutoff calibrators. No overlap was observed between cutoff levels and their ± 25% levels, with 95% statistical confidence. The precision of the 21 replicates was < 1% CV.

In semi-quantitative mode, recovery was less than 15% error of the nominal values and the precision of the 21 replicates was below 3% CV.

Linearity – Dilution Recovery

A high sample containing around 1000 ng/mL methadone metabolite was serially diluted in 10% increments with analyte-free urine. Recovery was within 10% of expected values, with a correlation coefficient of r = 0.9990.

Interferences

Results demonstrate that no significant interference was observed from endogenous and exogenous urine substances at the tested concentrations and the pH range of 4 to 11.

Specificity

Cross-reactivity to metabolites and structurally related compounds was tested on spiked samples in both the qualitative and semi-quantitative modes. All compounds tested negative, with rate below the 100 ng/mL cutoff rate and with dose recovered less than 100 ng/mL, indicating that the assay does not cross react with compounds at the tested concentrations.

Method Comparison

A total of 100 unaltered patient urine samples containing various concentrations of methadone metabolite were tested in both qualitative and semi-quantitative modes. Approximately 10% of the samples included in the study had concentrations between cutoff and 50% above the cutoff, and approximately 10% of the samples had concentrations between cutoff and 50% below the cutoff.

Samples were tested by:

- DRI Methadone Metabolite Assay (on-test method)
- CEDIA DAU EDDP Assay (predicate device)
- GC/MS (reference analytical method)

Qualitative Results

At the 100 ng/mL cutoff, the overall concordance between the DRI Assay and the predicate CEDIA Assay was 95%. The overall concordance between DRI and GC/MS was also 95%.

At the 300 cutoff, the overall concordance between the DRI and GC/MS was 99%.

Semi-quantitative Results

At the 100 cutoff, the overall concordance between the DRI Assay and the predicate CEDIA Assay was 99%. The overall concordance to GC/MS was also 99%.

At the 300 cutoff, the overall concordance between the DRI Assay and GC/MS was 100%.

CONCLUSION

As summarized, the DRI Methadone Metabolite (100/300) Assay is substantially equivalent to the CEDIA DAU EDDP Assay. 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
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Rockville MD 20850

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JAN 14 2009

Re: k081378
Trade Name: DRI® Methadone Metabolite (100/300) Assay, DRI® Methadone Metabolite Urine Calibrators, DRI® Methadone Metabolite Urine Control
Regulation Number: 21 CFR §862.3620
Regulation Name: Methadone Test System
Regulatory Class: Class II
Product Code: DJR, DKB, DIF
Dated: January 6, 2009
Received: January 7, 2009

Dear Mr. Rogers:

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,

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

Indications for Use

510(k) Number (if known): K081378

Device Name: DRI Methadone Metabolite (100/300) Assay

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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

510(k) K081378