JUN 2 3 2004

K040316

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:

Submitter:

Microgenics Corporation
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Fremont, CA 94538
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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:

February 6, 2004

Device Information:

Device Classification Name:	Radioimmunoassay, Buprenorphine
Common/Usual Name:	Buprenorphine Immunoassay Test System
Proprietary Name:	CEDIA® Buprenorphine Assay
Regulation Number:	21 CFR§862.3650
Regulatory Name:	Buprenorphine test system
Product Code:	DJG
Regulatory Class:	Class II

Predicate Devices:

The CEDIA® Buprenorphine Assay is substantially equivalent to other CEDIA test systems cleared by FDA, e.g., the CEDIA DAU 6-Acetylmorphine Assay (K001178), and GC/MS for its stated intended use.

Device Description:

The CEDIA® Buprenorphine Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

Intended Use:

The CEDIA® Buprenorphine assay is a homogenous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine.

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.

Comparison to Predicate Device(s):

The CEDIA® Buprenorphine Assay is substantially equivalent to other CEDIA test systems cleared by FDA, e.g., the CEDIA DAU 6-Acetylmorphine Assay (K001178), and GC/MS for its stated intended use.

Device Characteristics	Subject Device	Predicate Device(s) GC/MS and K001178
Intended Use	The CEDIA® Buprenorphine assay is a homogenous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine.	The CEDIA® DAU 6-Acetylmorphine Assay is a homogenous enzyme immunoassay for the in vitro qualitative or semi-quantitative determination of 6-Acetylmorphine in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of heroin use or overdose.
Analyte	Buprenorphine	6-AM
Matrix	Urine	Urine
Calibrator Form	Liquid	Liquid
Calibrator Levels	Five (5) Levels (0, 5, 20, 50 and 75 ng/mL)	Four (4) Levels (0,10,20 and 50 ng/mL)
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 and Package Insert for Kit and reconstituted reagents.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the CEDIA® Buprenorphine Assay is substantially equivalent to other CEDIA test system and GC/MS. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the CEDIA® Buprenorphine Assay is safe and effective for its stated intended use.

CEDIA® is a registered trademark of Roche Diagnostics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 3 2004

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

Re: k040316
Trade/Device Name: CEDIA® Buprenorphine Assay
CEDIA® Buprenorphine Calibrators
CEDIA® Buprenorphine Controls
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DLJ, LAS,
Dated: May 6, 2004
Received: May 10, 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 STATEMENT

510(k) Number (if known): K040316

Device name: CEDIA® Buprenorphine Assay
CEDIA® Buprenorphine Calibrators
CEDIA® Buprenorphine Controls

Indications for Use:

The CEDIA® Buprenorphine assay is a homogenous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine.

The CEDIA® Buprenorphine calibrators are used to calibrate the CEDIA® Buprenorphine Assay in human urine.

The CEDIA® Buprenorphine controls are used to qualify the CEDIA® Buprenorphine Assay in human urine.

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.

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

510(k) K040316