MAY - 2 2000

K994380

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
(510) 979-5029
Fax: (510) 979-5229

Contact Person: Neal Bellet

Date Prepared: April 20, 2000

2) Device name

Proprietary name: CEDIA® DAU AmphAssure Assay

Common name: Homogeneous enzyme immunoassay for the determination of amphetamines in urine.

Classification name: Amphetamine test system

3) Predicate device

We claim substantial equivalence to the TDx/TDxFLx Amphetamine/Methamphetamine II Immunoassay (K883707) manufactured by Abbott Laboratories Inc.

Continued on next page

4) Device Description

The CEDIA® DAU AmphAssure assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system.

This assay is based on the bacterial enzyme ß-galactosidase, which has been genetically engineered into two inactive fragments. 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.

The CEDIA DAU AmphAssure assay is a unique test for identification of amphetamines in urine and for the elimination of false positive results due to other cross-reactant substances. Most cross-reactive substances must be present in high concentrations compared to amphetamines in order to give a false-positive result in immunoassay based methods that detect amphetamines. AmphAssure employs the addition of a limited amount of a neutralizing antibody to amphetamine and methamphetamine to neutralize the signal in a true positive sample, without any effect on the signal from a sample containing a high concentration of cross-reactive substance. The neutralizing antibody does not bind the labeled conjugate in the assay, so that its primary effect is to reduce the signal resulting from amphetamines in the sample. Samples containing amphetamines can be distinguished from false-positive samples by the difference in signal before and after addition of the neutralizing antibody.

Two analyzer channels are programmed with identical test parameters for the CEDIA AmphAssure assay; reagents without neutralization antibodies are assigned to the first channel, and the reagents with neutralization antibodies are assigned to the second channel. A calculated test (channel three) is programmed to give the difference in results between the first and second channel. Calibrators, controls and patient samples are tested on both channels.

The device consists of following:

AmphAssure Reagents

1 EA Reconstitution Buffer
Piperazine-N, N-bis [2-ethanesulfonic acid] buffer, buffer salts, stabilizer, and preservative

1a EA Reagent
0.16 g/l Enzyme Acceptor (microbial), 7 mg/l mouse monoclonal antibodies reactive to d-amphetamine and 7 mg/l mouse monoclonal antibodies reactive to d-methamphetamine, buffer salts, detergent, and preservative

2 ED Reconstitution Buffer
Piperazine-N, N-bis [2-ethanesulfonic acid] buffer; buffer salts, and preservative

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Device Description continued

2a ED Reagent
7.1 µg/l Enzyme Donor (microbial) conjugated to d-amphetamine and 11.3 µg/l Enzyme Donor (microbial) conjugated to d-methamphetamine, 1.7g/l chlorophenol red-b-D-galactopyranoside, stabilizer, and preservative

3 EA Reconstitution Buffer
350 mg/l mouse monoclonal antibodies reactive to d-amphetamine and d-methamphetamine, Piperazine-N, N-bis [2-ethanesulfonic acid] buffer, buffer salts, stabilizer, and preservative

3a EA Reagent
0.16 g/l Enzyme Acceptor (microbial), 7 mg/l mouse monoclonal antibodies reactive to d-amphetamine and 7 mg/l mouse monoclonal antibodies reactive to d-methamphetamine, buffer salts, detergent, and preservative

4 ED Reconstitution Buffer
Piperazine-N, N-bis [2-ethanesulfonic acid] buffer; buffer salts, and preservative

4a ED Reagent
7.1 µg/l Enzyme Donor (microbial) conjugated to d-amphetamine and 11.3 µg/l Enzyme Donor (microbial) conjugated to d-methamphetamine,
1.7 g/l chlorophenol red-b-D-galactopyranoside, stabilizer, and preservative

AmphAssure Calibrator, Standard, and Control Set

- Upper Limit Standard
  15,000 ng/ml d-methamphetamine in normal urine with preservative
- Cut-off Calibrator
  375 ng/ml d-methamphetamine and 225K ng/ml pseudoephedrine in normal urine with preservative
- False Positive Control
  500K ng/ml pseudoephedrine in normal urine with preservative

AmphAssure Calibrator, Standard and Control Kit is designed for use with the AmphAssure assay only and will be packaged separately.

5) Intended use

The CEDIA® DAU AmphAssure Assay is a homogeneous enzyme immunoassay for the in vitro qualitative determination of amphetamines in human urine on automated clinical chemistry analyzers. This device is used as an accessory to immunoassay screening tests to reduce the number of false positive results needing confirmation testing. Measurements are used as an aid in the diagnosis and treatment of amphetamine use or overdose.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GCMS is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result particularly when preliminary positive test results are used.

6) Comparison to predicate device

The Microgenics Corporation CEDIA® DAU AmphAssure Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to TDx/TDx FLx Amphetamine /Methamphetamine II (K883707) manufactured by Abbott Laboratory Inc.

The following table compares the CEDIA® DAU AmphAssure Assay with the predicate device, TDx/TDx FLx Amphetamine /Methamphetamine II.

Similarities	Differences
• Both assays utilize a monoclonal antibody. • Both assays yield negative results to ephedrine, pseudoephedrine, and phenylpropanolamine at concentrations of 1 mg/mL. • Both assays are used to detect the presence of amphetamines in human urine • Both assays are run on automated clinical analyzers	• The two assays have different monitoring systems: AmphAssure (β-galactosidase hydrolysis of CPRG) TDX (Fluorescein tracer) • TDx uses periodate • AmphAssure assay is a two-channel system that generate a difference in rate when amphetamines are present. • TDx is semi-quantitative, whereas AmphAssure Assay is qualitative.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 2 2000

Mr. Andrew Morozovsky
VP of Regulatory and Compliance Systems
Microgenics Corporation
46360 Fremont Boulevard
Fremont, California 94538

Re: K994380
Trade Name: CEDIA DAU AMPHASSURE Assay
Regulatory Class: II
Product Code: DKZ, DKB
Dated: March 28, 2000
Received: March 29, 2000

Dear Mr. Morozovsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): N/A

Device Name: CEDIA® DAU AmphAssure Assay

Indications For Use:

The CEDIA® DAU AmphAssure Assay is a homogeneous enzyme immunoassay for the in vitro qualitative determination of amphetamines in human urine on automated clinical chemistry analyzers. This device is used as an accessory to immunoassay screening tests to reduce the number of false positive results needing confirmation testing. Measurements are used as an aid in the diagnosis and treatment of amphetamine use or overdose.

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Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994380

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)