AUG 2 7 2001

microgenics

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.

The assigned 510(k) number is: K012110.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
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Contact: Sherrie Rinne
Regulatory Specialist

Summary date: July 3, 2001

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): DRI® Ecstasy Enzyme Immunoassay

Name (usual): Ecstasy Enzyme Immunoassay

Classification: Amphetamines test system, 21 CFR 862.3100, Class II, DKZ (91)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

DRI Ecstasy Enzyme Immunoassay is substantially equivalent to CEDIA DAU Amphetamines/Ecstasy Assay (Microgenics Corporation, Fremont, CA), cleared under premarket notification K010496

DRI Ecstasy Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

The DRI Ecstasy Assay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies, which can detect ecstasy drugs in urine with minimal cross-reactivity to various amphetamine compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme, 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 causing a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use (21 CFR 807.92 (a)(5))

The DRI Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a Cutoff level of 500 ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and difference between DRI Ecstasy Enzyme Immunoassay and the predicate device follows.

Comparison Table:

DRI Ecstasy Enzyme Immunoassay vs CEDIA DAU Amphetamines/Ecstasy Assay

Device Name	CEDIA DAU Amphetamines/Ecstasy Assay (K010496)	DRI Ecstasy Enzyme Immunoassay (new device)
Indications for Use	The CEDIA DAU Amphetamines / Ecstasy Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative assay of amphetamines in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of amphetamines use or overdose. For use in clinical laboratories only. CEDIA Amphetamines/Ecstasy is uniquely designed to recognize samples that contain any of the Ecstasy Drugs, a group of ring substituted methylenedioxy analogues of amphetamine including 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxymethamphetamine (MDMA) and 3,4-methylenedioxyethylamphetamine (MDEA). This assay is intended for use on automated clinical analyzers. 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. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when	The DRI Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a Cutoff level of 500 ng/mL. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Device Name	CEDIA DAU Amphetamines/Ecstasy Assay (K010496)	DRI Ecstasy Enzyme Immunoassay (new device)
Indications for Use (cont.)	preliminary positive results are used. The CEDIA Amphetamines/ Ecstasy Assay provides a choice of two cutoff levels: 500 and 1000 ng/mL The assay is appropriate for testing under the Substance Abuse and Mental health Services Administration (SAMHSA, formerly NIDA) guidelines, which currently recommends a cutoff of 1000 ng/mL	
Method Principle	The assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. It is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.	The assay uses specific antibodies, which can detect ecstasy drugs in urine with minimal cross-reactivity to various amphetamine compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme, 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 causing a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.
Components	- Enzyme Acceptor Reagent - Enzyme Acceptor Buffer - Enzyme Donor Reagent - Enzyme Donor Buffer	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent
Risk to patient	In vitro device, positive results must be confirmed by GC/MS, or other method.	In vitro device, positive results must be confirmed by GC/MS, or other method.
Clinical Performance	Accuracy: %Agreement against a GC/MS reference method was 95% (159 true positives, 18 true negatives); Total Imprecision: Percent dose CVs across 6 levels of amphetamines concentrations were between 7.8% and 9.2%.	Accuracy: %Agreement against a GC/MS reference method was 100% (92 true positives, 18 true negatives); Total Imprecision: Percent dose CVs across 3 levels of ecstasy concentrations were ≤2.5%.

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))

The DRI Ecstasy Enzyme Immunoassay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of sensitivity, linearity, specificity, precision, and accuracy.

The assay showed good sensitivity with an LOD of 22 ng/mL.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as dose %CVs for both total and within-run testing were below 2.5%.

The DRI Ecstasy Enzyme Immunoassay is linear between 375 and 625 ng/mL The assay also shows good separation in the decision-making ranges between 375 and 625 ng/mL.

Accuracy studies showed good performance of the DRI Ecstasy Enzyme Immunoassay as compared to the GC/MS reference method. The %Agreement (Total) is 100%.

Specificity testing demonstrated that the DRI Ecstasy Enzyme Immunoassay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The DRI Ecstasy Enzyme Immunoassay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

Conclusions

The DRI Ecstasy Enzyme Immunoassay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of sensitivity, linearity, specificity, precision, and accuracy.

The assay showed good sensitivity with an LOD of 22 ng/mL.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as dose %CVs for both total and within-run testing were below 2.5%.

The DRI Ecstasy Enzyme Immunoassay is linear between 375 and 625 ng/mL. The assay shows good separation in the decision-making ranges between 375 and 625 ng/mL.

Accuracy studies showed excellent performance of the DRI Ecstasy Enzyme Immunoassay as compared to the GC/MS reference method. The %Agreement (Total) is 100%.

Specificity testing demonstrated that the DRI Ecstasy Enzyme Immunoassay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 7 2001

Ms. Sherrie Gene Rinne
Regulatory Specialist
Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 95438

Re: K012110
Trade/Device Name: DRI® Ecstasy Enzyme Immunoassy
Regulation Number: 21 CFR 862.3100
Regulatory Class: II
Product Code: DKZ
Dated: July 3 2001
Received: July 6, 2001

Dear Ms. Rinne:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K012110

Device Name: DRI® Ecstasy Enzyme Immunoassay

Indications for Use:

The DRI Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a Cutoff level of 500 ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012110