K993796

DEC 21 1999

510(k) Summary

Submitter's Name/Address:
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Contact Person:
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Date of Preparation of this Summary: November 1999

Device Trade or Proprietary Name: Rapid Drug Screen 5-Panel with Methamphetamine

Device Common/Usual Name or Classification Name: Rapid Drug Screen 5-Panel with Methamphetamine

Classification Number/Class: [no classification number]/Class II

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) is:_____

Predicate Devices: American Bio Medica "Rapid Drug Screen" 5-Panel test kit with Methamphetamine (K-984525)

Test Description:

All of the assays employed in the Rapid Drug Screen panels are based on the same principle of highly specific reaction between antigens and antibodies.

Each assay is a one-step, immunoassay in which a specially labeled drug (drug conjugate) competes with drug which may be present in the sample for the limited number of binding sites on the antibody. The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the "test" area. The formation of a visible line in the test area occurs when the test is below the cut-off for the drug.

When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex.. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the test area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine, and therefore, should be present in all reactions.

A negative urine will produce two colored bands, and a positive sample will produce only one band.

Intended Use:

The Rapid Drug Screen 5-Panel test with Methamphetamine is used for the qualitative detection of the following abused substances in human urine: d-Amphetamine, Benzoyl ecgonine, Cannabinoids, Opiates and Methamphetamines. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas chromatography/ mass spectrometry (GC/MS).

Performance Characteristics:

The Rapid Drug Screen 5-Panel test will detect drugs of abuse in human urine at the following levels:

d-Amphetamine	1000 ng/ml
Benzoyl ecgonine	300 ng/ml
Cannabinoids	50 ng/ml
Methamphetamines	1000 ng/ml
Opiates	300 ng/ml

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. All concentrations were verified by GC/MS. Each sample was tested four times, twice daily, for five days. The results confirmed the reproducibility of the Rapid Drug Screen 5-Panel with Methamphetamine performance.

Conclusion:

The "Rapid Drug Screen" 5-Panel with Methamphetamine is substantially equivalent to the previously cleared 5-Panel with Methamphetamine (K-984525) as demonstrated by results obtained in the studies. All of the five analytes in the kit have been cleared by the 510(k) process. There is no evidence of cross-reactivity when the five colloidal gold-antibody complexes are mounted in a common device side-by-side with physical separation of the individual channels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Mr. Henry Wells
Vice President, Product Development
American Bio Medica Corporation
300 Fairview Avenue
Hudson, New York 12534

Re: K993796
Trade Name: Rapid Drug Screen 5-Panel Test with Methamphetamines
Regulatory Class: II
Product Code: LDJ, DKZ, LAF, DJG, DIO
Dated: November 3, 1999
Received: November 9, 1999

Dear Mr. Wells:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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): K993796

Device Name: Rapid Drug Screen 5-Panel Test with Methamphetamines

Indications For Use:

"Rapid Drug Screen" 5-panel with cocaine, marijuana, opiates, amphetamine and methamphetamine is a lateral flow immunoassay for the simulatenous detection in urine of five abused drugs at stated detectable limits. (Each assay occupies a seperate channel). It is intended for use in the qualitative detection of d-Amphetamine (1000 ng/ml), Benzoyl ecgonine (300 ng/ml), Cannabinoids (50 ng/ml), Methamphetamines (1000 ng/ml) and Opiates (300 ng/ml).

"Rapid Drug Screen" is intended for professional use. It is not intended for over the counter sale to non-professionals. The assays are easy to perform, but should not be used without proper supervision. These immuno-assays are simplified qualatative screening methods that provides only a preliminary result for use in the need for aditional or confirmatory testing, i.e., gas-chromatography/mass spectrometry (GC/MS).

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

"Rapid Drug Screen" is not intended as a point of care test.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993796

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)