K023869

APR 3 0 2003

510 (k) Summary

Submitter's Name/Address:
American Bio Medica Corportion
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Contact Person:
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Date of Preparation of this Summary: November 14, 2002

Device Trade or Proprietary Name: 'RapidTec'-5M-Multiple Dip Test

Device Common/Usual Name or Classification Name: Multi Drug Test System

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

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

The assigned 510(k) number is:

Predicate Device: American Bio Medica Corp. 'Rapid Drug Screen'-9-Panel. (510(k) No. K012159.)

Test Description:

The assays employed in the 'RapidTec'-5M-Multiple Dip Test is based on the same principle of highly specific reactions between antigens and antibodies.

This assay is a one-step, competitive, immunoassay for the detection of marijuana, opiates, phencyclidine, cocaine and methamphetamine in human urine. The test device consists of a membrane strip onto which drug conjugates have been immobilized and a colloidal gold-multi-antibody complex 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 conjugates. Antibody-antigen reactions occur forming visible lines in the 'test' area.

When drug is present in the urine sample, the drug or metabolite will compete with its corresponding 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 antibody 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 on all reactions.

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

Intended use:

'RapidTec'-5M-Multiple Drug Test is used for the qualitative detection of the following abused substances in human urine: methamphetamines, benzoyl ecgonine, phencyclidine, opiates and cannabinoids. This immunoassay is a simplified 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:

'RapidTec'-5M-Multiple Dip Test will detect drugs of abuse in human urine at the following levels:

Methamphetamine	1000 ng/ml
Benzoyl ecgonine	300 ng/ml
Cannabinoids	50 ng/ml
Phencyclidine	25 ng/ml
Opiates	2000 ng/ml
	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 'RapidTec'-5M-Multiple Dip Test performance.

Conclusion:

'RapidTec'-5M-Multiple Dip Test is substantially equivalent to the previously cleared 'Rapid Drug screen'-9-Panel (510(k) No. K012159). Both systems utilize the same antibodies. The only difference is that in 'Rapid Drug Screen'-9-Panel, each assay occupies a separate channel, while in 'RapidTec'-5M-Multiple Dip Test each independent assay is 'stacked' in separate lines, one above the other.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 3 0 2003

Henry Wells, Ph.D.
V.P. Product Development
American Bio Medica Corporation
9110 Red Branch Road
Columbia, MD 21045

Re: k023869
Trade/Device Name: 'RapidTec'-5M-Multiple Dip Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: DJR, JXM, LDJ, DIG, LCM
Dated: February 24, 2003
Received: February 25, 2003

Dear Dr. Wells:

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K023869

DEVICE NAME: 'RapidTec'-5M-Multiple Dip Test

INDICATIONS FOR USE:

'RapidTec'-5M-Multiple Dip Test is a one-step lateral flow immunoassay for the simultaneous qualitative detection of methamphetamines, benzoyl ecgonine, cannabinoids, phencyclidine, and opiates in urine.

'RapidTec'-5Mmultiple Dip Test will detect these analytes at the following concentrations:

Methamphetamines:	1000 ng/ml
Benzoyl ecgonine	300 ng/ml
Cannabinoids	50 ng/ml
Phencylidine	25 ng/ml
Opiates	2000 ng/ml
	300 ng/ml

'Rapid Tec'-5M-Multiple Dip Test is intended for professional use. It is not intended for over-the-counter sale to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. 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).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023869

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

'RapidTec'-5M-Multiple Dip Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain. A more confirmed result. 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.