K992033

JUN 30 1999

**Attachment D**

# 510(k) Summary

**Submitter's Name/Address:**
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**Contact Person:**
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Product Development
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**Date of Preparation of this Summary**: June 1999

**Device Trade or Proprietary Name**: 'Rapid Drug Screen' 9-Panel

**Device Common/Usual Name or Classification Name**: Rapid Drug Screen 9-Panel

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

This 510(k) Summary is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

The assigned 510(k) is: _____

**Predicate Devices**: American BioMedica 'Rapid Drug Screen' 9-Panel test kit (510(k) No. K983770) and Biosite Diagnostics' Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants (510(k) No. K955935).

**Test Description:**

All of the assays employed in the Rapid Drug Screen 9-Panel are based on the same principle of the 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 an 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 negative.

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 of 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 9-Panel test is used for the qualitative detection of d-amphetamine; barbiturates; benzodiazepines; benzol ecognine; cannabinoids; d-methamphetamine; opiates; phencyclidine (PCP); and tricyclic antidepressants in human urine. 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:**

'Rapid Drug Screen' 9-Panel will detect 9 drugs in human urine at the following levels:

| | |
|---|---|
| d-Amphetamine | 750 ng/ml |
| Barbiturates | 300 ng/ml |
| Benzodiazepines | 300 ng/ml |
| Benzoyl ecognine | 225 ng/ml |
| Cannabinoids | |
| (11-nor-9-carboxy-delta-9-THC) | 50 ng/ml |
| Methamphetamine | 1000 ng/ml |
| Opiates (codeine) | 225 ng/ml |
| (morphine-3-glucuronide) | 225 ng/ml |
| Phencyclidine (PCP) | 19 ng/ml |
| Tricyclic antidepressants | 1000 ng/ml |

'Rapid Drug Screen' 9-Panel was compared to the previously 510(k) cleared 'Drug Screen' 9-Panel (510(k) No. K983770) and Biosite Triage Plus TCA tests. Ninety (90) samples were selected for evaluation, fifty (50) of which were found to be drug-free and forty (40) tested as positive by Syva EMIT-II. The forty positive specimens were identified but not quantified by HPLC. Both immunoassays correctly identified all of the

specimens which contained no drug as negative and determined the 40 drug-containing specimens to be positive.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. The results confirmed the reproducibility of the Rapid Drug Screen 9-Panel performance.

**Conclusion:**

The Rapid Drug Screen 9-Panel test is substantially equivalent to the previously-cleared 'Rapid Drug Screen' 9-Panel test (510(k) No. K983770) and the Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants (510(k) No. K955935), as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 30 1999

American Bio Medica
c/o Mr. John B. Dubeck, Esq.
Keller and Heckman LLP
1001 G Street NW, Suite 500W
Washington, DC 20001

Re: K992033
Trade Name: 'Rapid Drug Screen' 9-Panel
Regulatory Class: II
Product Code: DKZ, DIS, JXM, DJG, DIO, LDJ, LAF, LCL, LFG
Dated: June 16, 1999
Received: June 16, 1999

Dear Mr. Dubeck:

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): K992033

Device Name: "Rapid Drug Screen" 9-Panel

Indications For Use:

'Rapid Drug Screen' 9-Panel is a one-step, lateral flow immunoassay for the simultaneous detection of 8 abused substances and tricyclic antidepressants in urine. The "Rapid Drug Screen" 9-Panel test is intended for use in the qualitative detection of the following 9 drugs in human urine at the following levels:

| | |
|---|---|
| d-Amphetamine | 750 ng/ml |
| Barbiturates | 300 ng/ml |
| Benzodiazepines | 300 ng/ml |
| Benzoyl ecognine | 225 ng/ml |
| Cannabinoids | |
| (11-nor-9-carboxy-delta-9-THC) | 50 ng/ml |
| Methamphetamine | 1000 ng/ml |
| Opiates (codeine) | 225 ng/ml |
| (morphine-3-glucuronide) | 225 ng/ml |
| Phencyclidine (PCP) | 19 ng/ml |
| Tricyclic Antidepressants | 1000 ng/ml |

'Rapid Drug Screen' 9-Panel is intended for use by professional laboratories. 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).

**'Rapid Drug Screen' 9-Panel provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a more 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 positive results are used.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992033

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