APR 3 2000

510(k) Summary

Submitter's Name/Address:
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Date of Preparation of this Summary: June 30, 1999

Device Trade of Proprietary Name: 'RapidOne'-Barbiturate Test

Device Common/Usual Name or Classification Name: Barbiturate test system

Classification Number/Class 21 C.F.R. § 862.3150 (Class II)

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

The assigned 510(k) number is: K992451

Predicate Device: Forefront Diagnostics, Inc. 'Instacheck' Drug Screen -Barbiturate Test (510(k) No.K990107.)

Test Description:

The assay employed in the 'RapidOne'- Barbiturate Test is based on the same principle of highly specific reaction between antigens and antibodies.

This 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 anti-amphetamine monoclonal antibody has been immobilized. A colloidal gold-BSA-amphetamine complex is dried on a reagent pad. In the absence of any drug in the urine sample, the colloidal gold-complex moves with the urine by capillary action to contact the immobilized drug antibody. 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-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.

IntendedUse:

'RapidOne'- Barbiturate Test is used for the qualitative detection of secobarbital 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:

'RapidOne'-Barbiturate Test will detect 300 ng/ml of secobarbital in urine.

'RapidOne'-Barbiturate Test was compared to'Instacheck' Drug Screen-Barbiturate Test. 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 confirmed and quantified by GC/MS. Both immunoassays correctly identified all of the specimens which contained no drug as negative and determined the 40 drug-containing specimens, ranging in concentration of 310 ng/ml to 10000 ng/ml, to be positive.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative urines were also used. Each sample, at each concentration of analyte, was tested 4 times, twice daily, for 5 days.

Conc. (ng/ml)	#	Result	Precision
0	40	40/40 neg	>99%
150	40	40/40 neg	>99%
225	40	32/40 pos	>20%
300	40	40/40 pos	>99%
375	40	40/40 pos	>99%

Conclusion:

'RapidOne'-Barbiturate Test is substantially equivalent to'Instacheck' – Drug Screen – Barbiturate Test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 2000

Henry Wells, Ph.D.
Vice President of Product Development
American Bio Medica Corporation
122 Smith Road
Kinderhook, New York 12106

Re: K992451
Trade Name: 'RapidOne' – Barbiturate Test
Regulatory Class: II
Product Code: DIS
Dated: February 14, 2000
Received: February 15, 2000

Dear Dr. 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.

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): K992451

Device Name: 'RapidOne' - Barbiturate Test

Indications For Use:

'RapidOne' - Barbiturate Test is a one-step, lateral flow immunoassay for the detection of barbiturate in urine. 'RapidOne' - Barbiturate Test is intended for use in the qualitative detection of secobarbital in human urine at 300 ng/ml.

'RapidOne' - Barbiturate Test is intended for professional use. It is not intended for over the counter sale to non-professionals. 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).

'RapidOne' - Barbiturate Test 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.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992451

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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