NOV 2 0 2001

K012164

510(k) Summary

Submitter's Name/Address:
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Contact Person:
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Date of Preparation of this Summary: September 21, 2001

Device Trade or Proprietary Name: 'RapidOne'-Methadone Test

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

Classification Number/Class [no classification regulation]/ClassII

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

The assigned 510(k) number is: K012164

Predicate Device: Forefront Diagnostics, Inc. 'InstaCheck' Drug Screen-Methadone Test. (510(k) No. K992325)

Test Description:

The assay employed in the 'RapidOne'-Methadone' 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 that 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 a membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody 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-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.

Intended use:

'RapidOne'-Methadone Test is used for the qualitative detection of methadone 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., GC/MS.

Performance Characteristics:

'RapidOne'-Methadone Test will detect 300 ng/ml of methadone in urine.

'RapidOne'-Methadone Test was compared to 'InstaCheck'-Drug Screen-Methadone 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 as positive and quantified by GC/MS. Both immunaoassays correctly identified all the specimens that contained no drug as negative. GC/MS analyses were performed on samples that were screened as positive. Specimens, ranging in concentration of 146 to 1072 ng/ml were shown to be positive by both immunoassays.

Reproducibility was evaluated using control urines containing methadone concentrations above and below the stated cut-off. Forty (40) replicates were run at each concentration by three different operators.

Concentration (ng/ml)		RDS Result	
	#	Pos	Neg
No drug	120	0	120
150	120	6	114
225	120	106	14
375	120	120	0

Conclusion:

'RapidOne'-Methadone Test is substantially equivalent to Forefront Diagnostics, Inc. 'InstaCheck'-Methadone Test for the qualitative detection of methadone in human urine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Henry Wells, Ph.D.
American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106

NOV 2 0 2001

Re: k012164
Trade/Device Name: 'RapidOne' – Methadone Test
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: September 28, 2001
Received: October 4, 2001

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

NOV 2 0 2001

510(k) Number (if known): K012164

Device Name: 'RapidOne'-Methadone Test

Indications For Use:

'RapidOne'-Methadone Test is a one-step, lateral flow immunoassay for the detection of methadone in urine.

'RapidOne'-Methadone Test is intended for the qualitative detection of methadone in human urine at 300 ng/ml.

'RapidOne'-Methadone 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).

'RapidOne'-Methadone 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, particulary when preliminary results are used.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012164

(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)