



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 17 2004

Ms. Robin J. Helen, MS
Rapid Diagnostics, Inc.
c/o Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

Re: k033566
Trade/Device Name: MICROMEDIC® *Drugs of Abuse Panel Test*
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, and LCM
Dated: March 19, 2004
Received: March 24, 2004

Dear Ms. Hellen:

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.

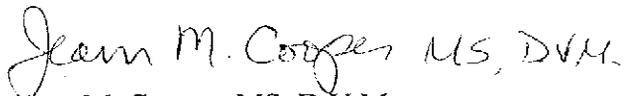
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

MICROMEDIC®

Drugs of Abuse Panel Test: DOA-9

STATEMENT FOR INDICATIONS FOR USE

510(k) Number (if known): _____

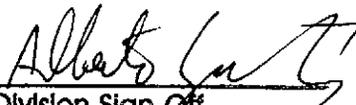
Device Name:

MICROMEDIC® Drugs of Abuse Panel Test

The MICROMEDIC® Drugs of Abuse Panel Test is an immunochromatographic one-step in-vitro test intended for the qualitative determination of up to nine different drug substances in human urine at the following cut-off levels (amphetamine, 1000 ng/ml; barbiturate [secobarbital], 300 ng/ml; benzodiazepine [oxazepam], 300 ng/ml; cocaine, 300 ng/ml; methadone, 300 ng/ml; methamphetamine, 1000 ng/ml; opiates, 2000 ng/ml; phencyclidine, 25 ng/ml; and cannabinoid, 50 ng/ml).

The MICROMEDIC® Drugs of Abuse Panel Test is intended for use in a point-of-care (POC) setting to include emergency hospitals and medical care facilities (i.e., emergency rooms, ambulances, etc.), as well as the workplace, criminal justice and transportation arenas, and walk-in, or mobile drug testing facilities. The MICROMEDIC® Drugs of Abuse Panel Test will provide a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. It is the responsibility of those organizations required to follow Department of Transportation (DOT) or the Substance Abuse and Mental Health Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA.

Concurrence of the CDRH, Office of Device Evaluation (ODE)


Division Sign-off

Prescription Use: X

Office of In Vitro Diagnostic Counter Use: _____
Device Evaluation and Safety

510(k) K033566