JUL 22 1999

K991504

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: 991504
1. Date of summary: July 1, 1999

2. Submitted by: Redwood Biotech 3573
Westwind Blvd.
Santa Rosa, CA 95403
TEL 707-577-7959
FAX 707-577-0365
Contact: Robert Mount

3. Device Name: Redi-Test Methamphetamine

4. Device Classification: Class II, 862.3610, Panel 91 Toxicology

5. Device description: The Redi-Test Methamphetamine is an immunochromatographic based one step *in vitro* test.

6. Intended Use: The Redi-Test Methamphetamine is a qualitative, one step immunochromatographic competitive assay used to screen human urine for the presence of d, methamphetamine at a cutoff concentration of 1000ng/ml The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

7. Substantial Equivalence: The Redi Test Methamphetamine was found substantially equivalent to the DRI, Amphetamine Enzyme Immunoassay. Both products are immunoassays and use specific antibodies. The DRI Amphetamine assay detects amphetamine and methamphetamine while the Redi-Test Methamphetamine detects methamphetamine. Both assays are preliminary screens and require confirmation with alternate methods such as GC/MS. The cut off sensitivity of both tests is 1000ng/mL. The tests demonstrated 94% agreement when 102 specimens (46 negative and 57 positive) were compared. Five of the six discrepant samples were positive by the DRI Amphetamine EIA, negative by the Redi-Test Methamphetamine and between 300 and 800ng/mL methamphetamine by GC/MS. One sample was negative by the DRI EIA and positive by the Redi-Test this sample had a GC/MS methamphetamine level of 1100ng/mL.

Conclusion:

The DRI Amphetamine Enzyme Immunoassay and the Redi-Test Methamphetamine are substantially equivalent in performance characteristics. The correlation between the two tests was 94%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1999

Redwood Biotech Inc.
Ms. Janis Freestone
c/o Advantage Diagnostics Corp.
2440 Leghorn Street
Mountain View, California 94043

Re: K991504
Trade Name: Redi-Test Methamphetamine
Regulatory Class: II
Product Code: LAF
Dated: June 21, 1999
Received: June 30, 1999

Dear Ms. Freestone:

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

510k Number:

Device Name:
Redi-Test Methamphetamine

Indications for Use:

The Redi-Test Methamphetamine is a qualitative, one step immunochromatographic competitive assay used to screen human urine for the presence of d, methamphetamine at a cutoff concentration of 1000ng/mL. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 991504

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use_____
(Per 21 CFR 801.109)