

## 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: K991883

1. Date of summary: May 20, 1999

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

3. Device Name: Redi-Test Opiates

4. Device Classification: CFR 21 862.3650, Class II, Panel 91 Toxicology

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

6. Intended Use: The Redi-Test Opiates is a qualitative, one step immunochromatographic competitive assay used to screen human urine for the presence of the opiate compounds including morphine at a cut off concentration of 300 ng/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 Opiates was found substantially equivalent to the DRI, Opiate Enzyme Immunoassay. Both products are immunoassays and use specific antibodies to detect various opiate compounds including morphine. Both assays are preliminary screens for human urine and require confirmation with alternate methods such as GC/MS. The sensitivity of the tests are similar, the DRI and Redi-Test both detect morphine and codeine at a cut off concentration of 300 ng/mL. The tests demonstrated >99% correlation when 100 specimens (50 negative and 50 positive, over the entire assay range) were compared. The tests are similar in sensitivity, specificity, accuracy and precision.

### Conclusion:

The Opiate Enzyme Immunoassay and the Redi-Test Opiates are substantially equivalent in performance characteristics. The correlation of the two tests was >99%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 15 1999

Advantage Diagnostics Corp.  
c/o Ms. Janis Freestone  
Redwood Biotech Inc.  
3573 Westwind Blvd.  
Santa Rosa, California 95403

Re: K991883  
Trade Name: Redi-Test Opiates  
Regulatory Class: II  
Product Code: DJG  
Dated: August 19, 1999  
Received: August 20, 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.

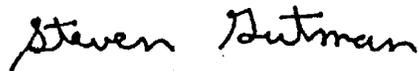
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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 Opiates

Indications for Use:

The Redi-Test Opiates is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of opiates at a cut off concentration of 300ng/mL. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

*Jean Cooper*  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K991883

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
(Per 21 CFR 801.109)

OR

Over the counter use