

DEC 27 1999

**SUN BIOMEDICAL LABORATORIES, INC.**

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
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510(k) CONTENT SUMMARY**1. Name of Manufacturer:**

Sun Biomedical Laboratories, Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, NJ 08012

2. Trade Name: Visualine®V Drugs of Abuse Dipstrip Panel for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine, and Phencyclidine and their metabolites in Human Urine Samples.**3. Common Name:**

An in-vitro immunoassay test by visual color comparison for the detection of Cocaine, Cannabinoids, Morphine, Methamphetamine, and Phencyclidine in human urine samples.

4. Regulation # and Classification:

Reg. #862-3170, Class II Device

5. Test Description:

The Visualine® V Drugs of Abuse Dipstrip Panel test is based on the principle of antigen-antibody complexation and is used for the analysis of Cocaine, Cannabinoids, Morphine, Methamphetamine, and Phencyclidine and their corresponding metabolites in human urine samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test urine delivered through a wicking action as the panel (holding the porous membrane) is dipped into the urine sample. The drug in the sample competes for the limited antibody sites on the colored microspheres. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive urine sample will inhibit the formation of precipitin at the probe site.

6. Comparison of Two Test Systems for Correlation Studies:

The Visualine®V Drugs of Abuse Dipstrip Panel for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine, and Phencyclidine assay is correlated to the individual Hitachi 717 instrument using Diagnostic Reagents, Inc. material. The following table illustrates the similarities and differences between the two assays.

	Hitachi 717 (Diagnostic Reagents, Inc EIA)	Visualine®V Drugs of Abuse Dipstrip Panel for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine, and Phencyclidine
Test Principle	Homogenous enzyme immunoassay	Competitive binding immunoassay
Sample/Sample Size	200 μ L urine	Approx. 200 μ L urine
Antibody	Polyclonal and Monoclonal	Polyclonal and Monoclonal
Tracer	Drug-Glucose-6-Phosphate Dehydrogenase	Ab Colloidal Complex
Detection Method	Change in absorbance (ΔA) value detected spectrophotometrically	Visual color precipitin formation
Test Run Time	10-20 minutes, dependent on test	5 minutes
Storage Requirement	2-8°C (36-46°F)	2-30°C (36-86°F)
Detection Level		
Cocaine	300 ng/ml	300 ng/ml
Cannabinoids	50 ng/ml	50 ng/ml
Morphine	300 ng/ml	300 ng/ml
Methamphetamine	1000 ng/ml	1000 ng/ml
Phencyclidine	25 ng/ml	25 ng/ml
Ancillary Equipment	717 Hitachi Analyzer, EIA Calibrators	none

7. Visualine®V Dipstrip Panel Performance Characteristics

- A. Correlation studies between Diagnostic Reagents, Inc. EIA individual assays and Visualine® V dipstrip Panel for Cocaine and its metabolites, Cannabinoids and its metabolites, Morphine and its metabolites, Methamphetamine, and Phencyclidine were conducted at Redwood Toxicology Laboratory, Santa Rosa California and Sun Biomedical Laboratories. Presumptive positive samples (tested on the Hitachi) for each drug were provided by Redwood and tested at Sun Biomedical Labs where blinded studies were conducted to determine the correlation between the two methodologies. Negative samples consisted of UTAK Laboratories Drug Free Urine

pool, Lot# 2647, and in-house negative urines tested with Sun Biomedical's Visualine® II product. Correlation with Hitachi 717 yielded the following data:

Cocaine:	Sensitivity	49 / 50	98 %
	Specificity	247 / 247	>99 %
	Efficiency	296 / 297	>99 %
Cannabinoids:	Sensitivity	50 / 50	>99 %
	Specificity	253 / 253	>99 %
	Efficiency	303 / 303	>99 %
Morphine:	Sensitivity	50 / 50	>99 %
	Specificity	257 / 257	>99 %
	Efficiency	307 / 307	>99 %
Methamphetamine:	Sensitivity	50 / 50	>99 %
	Specificity	255 / 255	>99 %
	Efficiency	305 / 305	>99 %
Phencyclidine:	Sensitivity	50 / 50	>99 %
	Specificity	255 / 255	>99 %
	Efficiency	305 / 305	>99 %

B. Specificity and Substances Detected:

The individual tests are specific to the labeled drug of abuse or structurally related compounds. The test detects Cocaine and its metabolites at 300 ng/ml, Cannabinoids and its metabolites at 50 ng/ml, Morphine and its metabolites at 300 ng/ml, Methamphetamine at 1000 ng/ml and Phencyclidine at 25 ng/ml.

C. Precision: Reproducibility studies for Cocaine, Cannabinoids, Morphine, Methamphetamine and PCP indicate:

Within run and run to run	> 99 %
Within day and day to day	> 99 %
Within lot and lot to lot	> 99 %

8. Attachments:

Correlation Studies	(Accuracy)	Section A
Specificity Studies	(Interference substances and cutoff levels of Each individual Drug of Abuse)	Section B
Sensitivity Studies	(Analytical studies)	Section C
Reproducibility Studies	(Precision)	Section D
Visualine® V Dipstrip Panel Package Insert		Section E
DRI Inserts for Hitachi 717		Section F
Label Copies		Section G
Stability Studies		Section H



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 1999

Ming Sun, Ph.D.
President
Sun Biomedical Laboratories, Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, New Jersey 08012

Re: K993485
Trade Name: Visualine® V Drugs of Abuse Dipstrip Panel
Regulatory Class: II
Product Code: DIO, LDJ, DJG, DKZ, LCM
Dated: October 11, 1999
Received: October 14, 1999

Dear Dr. Sun:

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 (Pre-market 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.

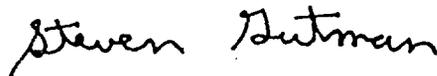
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known): K 993485

Device Name: Visualine V Drugs of Abuse Dipstrip Panel

Indications For Use:

Simultaneous qualitative visual tests for five (5) drugs of abuse:

Cocaine, Morphine, Cannabinoids, Methamphetamine and Phencyclidine and their metabolites in urine sample.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 993485

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format (-2-96))