

AUG 25 2003

## 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® Methadone DipStripTest3. Common Name:

An in-vitro immunoassay test by visual color comparison for the detection of Methadone and its metabolites in human urine samples. This test is intended for professional use only.

4. Regulation # and Classification:

Reg. #862-3620, Class II Device

5. Test Description:

The Visualine® Methadone DipStripTest is based on the principle of antigen-antibody complexation and is used for the analysis of Methadone and its metabolites in urine samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test urine delivered in a sample well on the device that holds the porous membrane. When the drug is present in the urine test sample, the drug or drug metabolite 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.

A reference or control line with a secondary antibody reaction is added to the membrane strip to indicate viability of the test. This control line should always be present. A negative urine sample will produce two colored lines and a positive urine sample will show only one, the control line.

6. Comparison of Two Test Systems for Correlation Studies:

The Visualine® Methadone DipStrip Test assay is correlated to the Hitachi Emit Methadone Assay. The following table illustrates the similarities and differences between the two assays.

	Hitachi® Methadone Assay	Visualine® Methadone DipStrip Test
Test Principle	Homogenous enzyme immunoassay	Competitive binding immunoassay
Sample/Sample Size	200 $\mu$ L urine	Approx. 150 $\mu$ L (3 drops) urine
Antibody	Polyclonal	Polyclonal
Tracer	Drug-Glucose-6-Phosphate Dehydrogenase	Ab Colloidal Complex
Detection Method	Change in absorbance ( $\Delta A$ ) 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	300 ng/ml Methadone	300 ng/ml Methadone
Ancillary Equipment	Hitachi Emit Calibrators	none

7. Visualine® Methadone DipStrip Test Performance Characteristics

A. Correlation studies between Hitachi Methadone Assay and Visualine® Methadone DipStrip Test were conducted at Sun Biomedical Laboratories with samples provided by The Lab, Inc. Correlation with Hitachi EmitII® Methadone Assay with cutoff at or above 300 ng/ml Methadone yielded the following data:

<u>Analytical</u> Sensitivity	56 / 56	= >99% Agreement
<u>Analytical</u> Specificity	76 / 76	= >99% Agreement
<u>Analytical</u> Efficiency	132 / 132	= >99% Agreement

B. Analytical Specificity and Substances Detected:

The test is specific to Methadone or structurally related compounds.  
The test detects Methadone at a concentration of 300 ng/ml.

C. Visualine® Methadone DipStrip Test Analytical Sensitivity:

The analytical sensitivity at 360 ng/ml Methadone read at 5 minutes is >99%.

D. Precision: Reproducibility studies indicate:

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

E. Analytical Studies versus precision and accuracy studies:

The Visualine® Methadone DipStrip Tests detect **methadone** at a cutoff of 300 ng/ml.

**F. Stability Statement:**

Visualine<sup>®</sup> Methadone DipStrip Test stability has been studied. The drug urine tests are tested every three months and reviewed for acceptance by the Quality Control Manager for up to a period of over two years. The acceptance criteria are as follows: A urine specimen containing 0 ng/ml of the analyte of interest will always render two distinct visible magenta lines, one test line and one control line. Samples containing 360 ng/ml of methadone show positive results >99% of the time, (yielding only the control line). Visualine<sup>®</sup> Methadone DipStrip Test Kits are stable within their marked expiration date and under the storage conditions as described in the package insert.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**AUG 25 2003**

Ms. Mary Ann Bompadre  
Regulatory Manager  
Sun Biomedical Laboratories Inc.  
604 VPR Center  
1001 Lower Landing Road  
Blackwood, NJ 08012

Re: k023856  
Trade/Device Name: Visualine<sup>®</sup> Methadone DipStrip Test  
Regulation Number: 21 CFR 862.3620  
Regulation Name: Methadone test system  
Regulatory Class: Class II  
Product Code: DJR  
Dated: June 6, 2003  
Received: July 22, 2003

Dear Ms. Bompadre:

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.

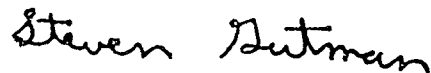
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure



# SUN BIOMEDICAL LABORATORIES, INC.

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1001 LOWER LANDING RD  
BLACKWOOD, NJ, USA 08012  
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Tel: 856.401.1080  
Fax: 856.401.1090

510 (k) Number: K 023856

DEVICE NAME: Visualine® Methadone DipStrip Test

INDICATIONS FOR USE: The Visualine® Methadone DipStrip Test is used for qualitative testing for the presence of Methadone in human urine samples at or above 300 ng/ml. This test provides only a preliminary screening result; a more specific alternative method should be used to confirm the test result. This test is intended for use by medical professionals.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use   
(Optional Format 1-2-96)

*Albert Smith*  
(Division Sign-Off) *for* *Ilan Cooper*  
Division of Clinical Laboratory Devices  
510(k) Number K 023856