APR 19 2010

## 5. 510(k) Summary

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

The Assigned 510(k) number is: K092048

**Submitter:**

Biosite, Inc.

9975 Summers Ridge Road

San Diego, California 92121

Tel.: 858-805-2278

Fax: 858-695-7100

**Date:**

**April 12, 2010**

**Contact Person:**

Lisa Chicorka

**Product Names:**

One Step EDDP (Methadone Metabolite) Test Strip

| | |
|---|---|
| **Common Name:** | Immunochromatographic Test for the 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) in urine |
| **Regulation Name:** | Methadone Test System |
| **Product Code:** | DJR |
| **Regulatory Class:** | Class II |
| **Classification Regulation:** | 21 CFR 862.3620 |

**Intended Use**

The One Step EDDP (Methadone Metabolite) Test Strip is a rapid immunochromatographic immunoassay for the qualitative detection of 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), an inactive metabolite of methadone, at a designated cutoff concentration of 300 ng/mL. This product is used to obtain a visual, qualitative result and is intended for professional use and professionals at point of care sites.

This assay provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**Description:**

The One Step EDDP (Methadone Metabolite) Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. EDDP, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized EDDP conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the EDDP level exceeds 300 ng/mL because it will saturate all the binding sites of anti-EDDP antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region. This confirms sufficient specimen volume, adequate membrane wicking and correct

**Comparison to a Predicate Device:**

The predicate devices, ACON MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device (K012595) are intended for the detection of Methadone in urine with a cutoff of 300 ng/mL. The One Step EDDP (Methadone Metabolite) Test Strip is to be used for the detection of the Methadone Metabolite EDDP at a cutoff of 300 ng/mL. The same test principle and technology of these rapid diagnostic tests enables substantial equivalence. Another predicate device, the DRI Methadone Metabolite Enzyme Assay (K023617), is a Liquid Homogeneous Enzyme Assay which detects EDDP with results being obtained spectrophotometrically. Although the test principle differs, the same metabolite is to be detected at the same cut-off (300 ng/mL) as does the One Step EDDP (Methadone Metabolite) Test Strip. Therefore, the DRI Methadone Metabolite Enzyme Assay is also used in the substantial equivalence discussion.

A predicate device with identical technology is K081378 -Bionexia™ Single and Multi-Strip Cassette/Dipstick DOA Screen Panels., which are rapid immunochromatographic immunoassays for the qualitative detection of 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine with a cutoff of 100 ng/mL (EDDP) (and other drugs). The submitter is Applied DNA Technologies Inc. BioClinical Performance Data of the One Step EDDP (Methadone Metabolite) Test Strip was compared with the reference method GC/MS and the DRI® Methadone Metabolite Assay (cutoff 300 ng/mL) manufactured by Microgenics, Inc.

**Performance Characteristics**

The One Step EDDP (Methadone Metabolite) Test Strip was evaluated to determine the performance characteristics of the test. Various studies were performed to determine the Analytical Sensitivity, Cross Reactivity, Interference Substances, Urinary pH, Urinary Specific Gravity, Reading Time Flexibility, Sample Flexibility, Temperature Flexibility, Specimen Storage, Recovery, Stability, POL Study and Clinical Study.

**Accuracy**

The performance of the One Step EDDP (Methadone Metabolite) Test Strip was evaluated and compared to GC/MS by three external clinical study sites, with 3 different employees performing the testing.

**Table 1 One Step EDDP (Methadone Metabolite) Test Strip vs. GC/MS Analysis**

| Method | | | Specimen Cut -off Range by GC/MS Analysis | | | | | % Agreement with GC/MS Analysis |
|---|---|---|---|---|---|---|---|---|
| | | | Negative | Low negative (<-50% cutoff) | Near cutoff negative (-50% cutoff to cutoff) | Near cutoff positive (cutoff to +50% cutoff) | High positive (> +50% cutoff) | |
| EDDP Test Strip | Clinical Site | Positive | 0 | 0 | 3 | 8 | 70 | 98% (180/183) (95% - 100%)* |
| | | Negative | 100 | 1 | 1 | 0 | 0 | |
| | Clinical Site | Positive | 0 | 0 | 4 | 8 | 70 | 98% (179/183) (94% - 99%)* |
| | | Negative | 100 | 1 | 0 | 0 | 0 | |
| | Clinical Site | Positive | 0 | 0 | 4 | 8 | 70 | 98% (179/183) (90% - 97%)* |
| | | Negative | 100 | 1 | 0 | 0 | 0 | |
| Over All Agreement With GC/MS Analysis | | | | | | | | 98% (538/5549) (96% - 99%)* |

* Denotes 95% confidence intervals

Overall % Agreement with GC/MS is 98%.

**Analytical Sensitivity**

A drug-free urine pool was spiked with EDDP at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL, 450 ng/mL and 900 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

**Table 2 One Step EDDP (Methadone Metabolite) Test Strip**

| EDDP Concentration (ng/mL) | Percent of Cut-off | n | Visual Result | |
|---|---|---|---|---|
| | | | Negative | Positive |
| 0 | 0% | 90 | 90 | 0 |
| 150 | -50% | 90 | 90 | 0 |
| 225 | -25% | 90 | 90 | 0 |
| 300 | Cut-off | 90 | 51 | 39 |
| 375 | +25% | 90 | 14 | 76 |
| 450 | +50% | 90 | 0 | 90 |
| 900 | +300% | 90 | 0 | 90 |

**Risk Analysis**

Risk analysis was performed on the One Step EDDP (Methadone Metabolite) Test Strip and results were found acceptable.

**Conclusion:**

The One Step EDDP (Methadone Metabolite) Test Strip is a rapid chromatographic immunoassay for detection of Methadone Metabolite in human urine at a designated cutoff concentration of 300 ng/mL. The EDDP Test Strip is used to provide only a preliminary analytical result. All positive test results obtained with this device must be confirmed by another test method, preferably GC/MS. It is intended for healthcare professionals including professionals at point-of-care sites to assist in the determination of drug compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Biosite, Inc.
c/o Lisa Chicorka
9975 Summers Ridge Road
San Diego, CA 92121

APR 19 2010

Re: k092048
Trade Name: One Step EDDP (Methadone Metabolite) Test Strip
Regulation Number: 21 CFR §862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Codes: DJR
Dated: April 12, 2010
Received: April 13, 2010

Dear Ms. Chicorka:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

## Indications for Use

510(k) Number (if known): K092048

Device Name: One Step EDDP (Methadone Metabolite) Test Strip

**Intended Use**

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Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092048