JUN 22 2006

K060791

II. 510(k) Summary of Safety and Effectiveness

In accordance with the provisions of Section 4 of the Safe Medical Devices Act of 1990 and 21 CFR 807.92, the following summary is provided. Biosite requests that this document be maintained CONFIDENTIAL until such time that the product is cleared by the Food and Drug Administration via the 510(k) Notification Process and in accordance with the provisions of the Act.

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
Telephone:	(888) 246-7483
Fax:	(858) 586-7543
Contact Person:	Robin Weiner
Date Summary Prepared:	03/22/06

B. Device Names

Triage® TOX Drug Screen

C. Predicate Devices

Biosite Triage® 8 Panel for Drugs of Abuse [FDA file number K973784]
Biosite Triage® TOX Drug Screen [FDA file number K043242]

D. Device Description and Intended Use

The Triage® TOX Drug Screen Methadone assay is a fluorescence immunoassay intended to be used with the Triage MeterPlus for the point-of-care qualitative determination of methadone in urine.

The Triage Methadone assay is identical in principle, reagents and procedure to the previously cleared Triage TOX Drug Screen [FDA file number K043242]. The only difference between the two tests is that an assay for methadone has been added

E. Summary of Comparison Data

A method comparison of the Triage TOX Drug Screen Methadone assay with the Biosite Triage 8 Panel for Drugs of Abuse was performed using 102 specimens obtained from clinical sources. The overall agreement was 96.1%. Discordant samples were determined by GC/MS to contain l-methadone at concentrations greater than 175 ng/mL (the established threshold concentration of the GC/MS method for the l-methadone enantiomer) but less than the threshold concentration of the Triage 8 Panel for Drugs of Abuse (300 ng/mL). Based on this, the percent agreement versus the claimed specificity for the distinct methadone enantiomers would be 100%. The analytical performance characteristics of the assay were equivalent with predicate methods.

F. Conclusion

In conclusion, these studies demonstrate the substantial equivalence of the Triage TOX Drug Screen Methadone assay to existing products already marketed for detecting the presence of various drugs of abuse. They further demonstrate the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 2006

Ms. Robin Weiner
Vice President, Regulatory and Government Affairs
Biosite Incorporated
9975 Summers Ridge Road
San Diego, CA 92121

Re: k060791
Trade/Device Name: Triage® TOX Drug Screen
Regulation Number: 21 CFR§862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: June 6, 2006
Received: June 9, 2006

Dear Ms. Weiner:

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).

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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

510(k) Number (if known): K060791

Device Name: Triage® TOX Drug Screen

Indications For Use:

The Triage TOX Drug Screen is a fluorescence immunoassay intended to be used with the Triage Meters for the point-of-care qualitative determination of the presence of drug and/or the major metabolites above the threshold concentrations of up to 10 distinct drug classes, including assays for acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC and tricyclic antidepressants in urine.

The acetaminophen/paracetamol assay will yield positive results when acetaminophen/paracetamol is ingested at or above therapeutic doses.

The threshold concentrations are provided below:

Acetaminophen/Paracetamol	**APAP**	5 µg/mL
Amphetamines	**AMP**	1000 ng/mL
Methamphetamines	**mAMP**	1000 ng/mL
Barbiturates	**BAR**	300 ng/mL
Benzodiazepines	**BZO**	300 ng/mL
Cocaine	**COC**	300 ng/mL
Methadone	**MTD**	300 ng/mL
Opiates	**OPI**	300 ng/mL
Phencyclidine	**PCP**	25 ng/mL
THC	**THC**	50 ng/mL
Tricyclic Antidepressants	**TCA**	1000 ng/mL

This test provides only preliminary test results. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmatory method.

A quantitative serum acetaminophen/paracetamol measurement is the common confirmatory method for preliminary positive acetaminophen/paracetamol results.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060791