FEB 2 8 2005

K 043242

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) process and in accordance with the provisions of the Act.

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8350
Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	February 22, 2005

B. Product

Triage® TOX Drug Screen (K043242)

C. Predicate Devices

Triage TOX Drug Screen, FDA File Number 510(k) 012745

D. Device Description and Intended Use

The Triage® TOX Drug Screen is a fluorescence immunoassay intended to be used with the Triage MeterPlus for the point-of-care qualitative determination of the presence of major metabolites above the threshold concentrations of up to 8 distinct drug classes, including assays for acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, 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
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 a preliminary test result. 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 common confirmatory method.

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

E. Summary of Comparison Data

A method comparison of acetaminophen results with GC/MS was performed using 102 specimens, with 20 specimens within ±25% of the cutoff concentration. The overall agreement is 97.1%. The three discordant samples were positive on the Triage TOX Drug Screen and were within 10% below the cutoff by GC/MS. The analytical performance characteristics of the assay were equivalent to predicate methods.

F. Conclusion

In conclusion, these studies demonstrate the substantial equivalence of the Triage TOX Drug Screen to existing products already marketed for detecting the presence of various drugs of abuse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2005

Jeffrey R. Dahlen, Ph.D.
Director, Clinical & Regulatory Affairs
Biosite Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k043242
Trade/Device Name: Triage® TOX Drug Screen
Regulation Number: 21 CFR 862.3030
Regulation Name: Acetaminophen test system
Regulatory Class: Class II
Product Code: LDP, DKZ, DIS, JXM, JXO, LAF, DJG, LCM, LDJ, LFG
Dated: February 15, 2005
Received: February 16, 2005

Dear Dr. Dahlen:

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,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
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): K043242

Device Name: Triage TOX Drug Screen

Indications For Use:

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Prescription Use (Per 21 CFR 801.109) X AND/OR Over-The-Counter Use (Per 21 CFR 807 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) K043242