JUN 2 5 2004

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: **K040437**

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:	6/24/04

B. Device Names

1. Trade Name

   Triage® Profiler S.O.B. Panel

2. Common / Usual Name

   Triage® Profiler S.O.B. Panel

3. Classification Name

   Fluorometric Method, CPK or Isoenzymes (862.1215)
   Product Code JHX

   Immunoassay Method, Troponin Subunit (862.1215)
   Product Code MMI

   Myoglobin, Antigen, Antiserum, Control (866.5680)
   Product Code DDR

   Test, Natriuretic Peptide (862.1117)
   Product Code NBC

   Fibrinogen/Fibrin Degradation Products Assay (864.7320)
   Product Code GHH

C. Predicate Devices

Triage® Cardiac Panel (K973126)
Triage® BNP Test (K021317)
Dade Behring Stratus CS DDMR TestPak (K022976)

D. Device Description and Intended Use

The Triage® Profiler S.O.B. (Shortness of Breath) Panel is a fluorescence immunoassay to be used with the Triage® Meter Plus for the quantitative determination of creatine kinase MB, myoglobin, troponin I, B-type natriuretic peptide, and cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury), an aid in the diagnosis and assessment of severity of heart failure, an aid in the assessment and evaluation of patients suspected of disseminated intravascular coagulation (including pulmonary embolism) and other non-specific thromboembolic events, and an aid in the risk stratification of patients with acute coronary syndromes.

E. Summary of Comparison Data

A method comparison of the CK-MB, troponin I, myoglobin, and BNP assays demonstrated that the assays on the Triage Profiler S.O.B. panel are equivalent to the same assays in the predicate methods. A method comparison of D-dimer results was performed using 180 specimens throughout the measurable range of the test. A Passing-Bablok regression analysis of the results yielded a linear relationship with a slope of 0.999, an intercept of –85.89 and a correlation coefficient of 0.92. The analytical performance characteristics for each of the assays were equivalent with the predicate methods.

F. Conclusion

The assays on the Triage Profiler S.O.B. Panel are substantially equivalent to the predicate methods. The evaluation has led to assurance that the Triage Profiler S.O.B. Panel is safe and effective for the intended use and no new issues of safety and effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2004

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

Re: k040437
Trade/Device Name: Triage® Profiler S.O.B. Panel
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/Fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP, NBC,MMI, JHX, DDR
Dated: June 1, 2004
Received: June 2, 2004

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 (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,

Jean M. Cooper MS, D.V.M.

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): K040437

Device Name: Triage® Profiler S.O.B. Panel

Indications For Use:

The Triage® Profiler S.O.B. (Shortness of Breath) Panel is a fluorescence immunoassay to be used with the Triage® Meter Plus for the quantitative determination of creatine kinase MB, myoglobin, troponin I, B-type natriuretic peptide, and cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury), an aid in the diagnosis and assessment of severity of heart failure, an aid in the assessment and evaluation of patients suspected of disseminated intravascular coagulation (including pulmonary embolism) and other non-specific thromboembolic events, and an aid in the risk stratification of patients with acute coronary syndromes.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040437