510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042723

B. Purpose for Submission:
Modification to Indications for Use of Triage® Profiler S.O.B. Panel (k040437). The sponsor has modified the portion of the Indications for Use statement pertaining to the D-Dimer test from: "…an aid in the assessment and evaluation of patients suspected of disseminated intravascular coagulation (including pulmonary embolism) and other non-specific thromboembolic events…" to "…an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism." The change was made for clarification of the language and to agree with the wording in the Indications for Use statement for the Triage® D-Dimer Test (k042890), cleared November 29, 2004.

C. Analyte:
D-Dimer
CK-MB
Troponin I
Myoglobin
BNP

D. Type of Test:
Quantitative fluorescence immunoassay

E. Applicant:
Biosite Incorporated

F. Proprietary and Established Names:
Triage® Profiler S.O.B. Panel

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.7320, Fibrinogen/fibrin degradation products assay
   21 CFR 862.1215, Immunoassay Method, Troponin Subunit
   21 CFR 862.1215, Fluorometric method, CPK or isoenzymes
   21 CFR 866.5680, Myoglobin, antigen, antiserum, control
   21 CFR 862.1117, Test, Natriuretic Peptide

2. Classification:
   Class II

3. Product Code:
   DAP, MMI, JHX, DDR, NBC

4. Panel:
   81 Hematology, 75 Chemistry, 82 Immunology

H. Intended Use:

1. Intended use(s):
   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 having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism, and an aid in the risk stratification of patients with acute coronary syndromes.

2. Indication(s) for use:
   See Intended Use above

3. Special condition for use statement(s):
   Prescription Use

4. Special instrument Requirements:
   Triage® Meter Plus

I. Device Description:

The Triage® Profiler S.O.B. Test Device contains all the reagents necessary for the simultaneous quantification of D-dimer, CK-MB, myoglobin, troponin I, and BNP in plasma and whole blood. The test device contains murine monoclonal and polyclonal antibodies against CK-MB, murine monoclonal and polyclonal antibodies against myoglobin, murine monoclonal and goat polyclonal antibodies against troponin I, murine monoclonal antibodies to D-dimer, and murine monoclonal and polyclonal antibodies against BNP labeled with a fluorescent dye and immobilized on the solid phase, and stabilizers.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Triage® Profiler S.O.B. Panel

2. Predicate K number(s):
   k040437

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Principle	Fluorescence immunoassay	Same
Instrument	Triage® Meter Plus	Same
Differences		
Item	**Device**	**Predicate**
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 having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism, and an aid in the risk stratification of patients with acute coronary syndromes.	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.

K. Standard/Guidance Document Referenced (if applicable):
None referenced

L. Test Principle:
The Triage® Profiler S.O.B. Test Device contains all the reagents necessary for the simultaneous quantification of the cardiac proteins D-dimer, CK-MB, myoglobin, troponin I, and BNP in whole blood and plasma specimens using EDTA as the anticoagulant. After addition of the sample to the sample port, the cells are separated from the plasma via a filter contained in the device. A predetermined quantity of plasma is allowed to react with fluorescent antibody conjugates within the reaction chamber. After sufficient incubation has occurred, the reaction mixture flows down the device detection lane. Complexes of the analytes and fluorescent antibody conjugates are captured on discrete zones resulting in binding assays that are specific for each analyte. The concentration of the analyte in the specimen is directly proportional to the fluorescence detected.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    See k040437
    b. *Linearity/assay reportable range:*
    See k040437
    c. *Traceability (controls, calibrators, or method):*
    The Triage® Profiler S.O.B. Panel has been standardized using purified protein preparations of D-dimer, CK-MB, myoglobin, troponin I, and BNP based on the mass (concentration) of analyte present in EDTA-anticoagulated plasma.
    d. *Detection limit:*
    See k040437.
    e. *Analytical specificity:*
    See k040437
    f. *Assay cut-off:*
    See k040437
2. Comparison studies:
    a. *Method comparison with predicate device:*
    See k040437
    b. *Matrix comparison:*
    See k040437
3. Clinical studies:
    a. *Clinical sensitivity:*
    See k040437
    b. *Clinical specificity:*
    See k040437
    c. *Other clinical supportive data (when a and b are not applicable*
4. Clinical cut-off:
    See k040437

5. Expected values/Reference range:
   See k040437

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.