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

A. 510(k) Number:

k080269

B. Purpose for Submission:

Modification to the Triage® Profiler S.O.B. Panel (k040437) and the Triage® Cardio ProfilER Panel (k030286) to expand the portion of the Indications for Use statement pertaining to the BNP Test to add "as an aid in the risk stratification of patients with heart failure" and labeling revisions to BNP portion of the labeling to include a section titled "Prognostic Utility in Patients with Heart Failure." The identical changes to the Indications for Use and the labeling revisions to the "Prognostic Utility in Patients with Heart Failure" section of the labeling were cleared for the Triage® BNP Test in k051787. There have been no changes to the test performance, design, reagents and manufacture. No changes have been made to the D-Dimer, Troponin I, CK-MB and Myoglobin assays.

C. Measurand:

B-type Natriuretic Peptide (BNP)

D-Dimer

CK-MB

Troponin I

Myoglobin

D. Type of Test:

Quantitative fluorescence immunoassay

E. Applicant:

Biosite Incorporated

F. Proprietary and Established Names:

Triage® Profiler S.O.B. ™ (Shortness of Breath Panel)

Triage® CardioProfilER® Panel

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1117, Test, Natriuretic Peptide

   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

2. Classification:

   Class II

3. Product code:

   NBC, DAP, MMI, JHX, DDR

4. Panel:

   81 Hematology, 75 Chemistry, 82 Immunology

H. Intended Use:

1. Intended use(s):

   See Indications for Use below

2. Indication(s) for use:

   The Triage® Profiler S.O.B. (Shortness of Breath) Panel is a fluorescence immunoassay to be used with the Triage Meters 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 risk stratification of patients with 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® CardioProfilER® Panel is a fluorescence immunoassay to be used with the Triage Meters for the quantitative determination of creatine kinase MB, myoglobin, troponin I and B-type natriuretic peptide in EDTA whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury), the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), an aid in the risk stratification of patients with heart failure and for the risk stratification of patients with acute coronary syndromes.

3. Special conditions for use statement(s):

   The device is for prescription use

4. Special instrument requirements:

   Triage MeterPlus

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 whole blood and EDTA plasma samples. The Triage® Profiler S.O.B. Panel is a single-use device containing 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. Additionally, there are built-in control features that ensure that the test was performed properly and the reagents were functionally active.

The Triage® Cardio ProfilER test device contains all the reagents necessary for the simultaneous quantification of CK-MB, myoglobin, troponin I and BNP in whole blood and EDTA plasma samples. The Triage® Cardio ProfilER Panel is a single-use device containing murine monoclonal and polyclonal antibodies against CK-MB, murine monoclonal and polyclonal antibodies against myoglobin, murine monoclonal and goat polyclonal antibodies against troponin I and murine monoclonal and polyclonal antibodies against BNP labeled with a fluorescent dye and immobilized on the solid phase, and stabilizers. Additionally, there are built-in control features that ensure that the test was performed properly and the reagents were functionally active.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Triage® BNP Test

Triage® Profiler S.O.B. Panel

Triage® CardioProfilER® Panel

2. Predicate K number(s):

k051787

k042723

k030286

3. Comparison with predicate:

Similarities		
Item	k080269	k051787
Test principle, procedure and reagents	Same	Same
Indications for Use	Use of BNP as an aid in the: Diagnosis of heart failure Assessment of severity of heart failure Risk stratification of patients with acute coronary syndromes Risk stratification of patients with heart failure	Same

Differences		
Item	k080269	k030286/k042723
Indications for Use	Use of BNP as an aid in the: Diagnosis of heart failure	Use of BNP as an aid in the: Diagnosis of heart failure Assessment of severity of

Differences		
Item	k080269	k030286/k042723
	Assessment of severity of heart failure Risk stratification of patients with acute coronary syndromes Risk stratification of patients with heart failure	heart failure 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. Panel is a fluorescence immunoassay for the quantitative determination of 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.

The Triage® CardioProfilER Panel is a fluorescence immunoassay for the quantitative determination of 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:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   b. *Linearity/assay reportable range:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   d. *Detection limit:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   e. *Analytical specificity:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   f. *Assay cut-off:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

2. Comparison studies:

   a. *Method comparison with predicate device:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   b. *Matrix comparison:*

      Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

3. Clinical studies:

   a. Clinical Sensitivity:

   Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   b. Clinical specificity:

   Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

   c. Other clinical supportive data (when a. and b. are not applicable):

   The changes to the portion of the Indications for Use pertaining to BNP and the labeling revisions to the "Prognostic Utility in Patients with Heart Failure" section of the labeling were cleared for the Triage® BNP Test in k051787.

   To support the additional intended use, the sponsor provided five peer-reviewed articles from the scientific literature assessing the clinical utility of BNP measurements as an aid in the risk stratification of patients with heart failure. All five studies utilized the Biosite Triage BNP device in their test method.

   In one additional paper titled "How well does B-type natriuretic peptide predict death and cardiac events in patients with heart failure: systematic review," J.A. Doust et al. (British Medical Journal, volume 330, 19 March 2005) performed a systematic evidence-based medicine review of the literature. The review included 24 studies in all. While the review included studies with different study designs and test methods (BNP and NT-proBNP), the five articles previously mentioned were part of the review. The authors concluded that BNP was a strong prognostic indicator for patients with heart failure.

   All literature references are cited in the sponsor's labeling.

4. Clinical cut-off:

   Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

5. Expected values/Reference range:

   Previously demonstrated for Triage® Profiler S.O.B. Panel in k042723 and Triage® CardioProfilER® Panel in k030286.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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

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