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

A. 510(k) Number:

k052789

B. Purpose for Submission:

Modification to the Triage BNP Test for the Beckman Coulter Immunoassay Systems (k033383) to expand the Indications for Use as an aid in the risk stratification of patients with heart failure.

C. Measurand:

B-type Natriuretic Peptide

D. Type of Test:

Quantitative

E. Applicant:

Biosite Inc.

F. Proprietary and Established Names:

Triage BNP Test for the Beckman Coulter Immunoassay Systems

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1117, B-type natriuretic peptide test system

2. Classification:

   Class II

3. Product code:

   NBC

4. Panel:

   (75) Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use

2. Indication(s) for use:

   The Triage BNP test is intended for use with Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725 and UniCel Dxl 800) for the *in vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to heart failure). The test is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.

3. Special conditions for use statement(s):

   Prescription Use only

4. Special instrument requirements:

   Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725 and UniCel Dxl 800)

I. Device Description:

The test kit contains three reagents, R1a, R1b, and R1c. R1a consists of paramagnetic particles coated with mouse omniclonal anti-human BNP antibody suspended in TRIS buffered saline, with bovine serum albumin (BSA), 0.1% ProClin 300, and < 0.1% sodium azide; R1b consisits of purified mouse and goat IgG in TRIS buffered saline with 0.1% ProClin 300 and < 0.1% sodium azide; R1c consists of mouse monoclonal anti-human BNP antibody-alkaline phosphatase bovine conjugate in PBS buffered saline with BSA, 0.1% ProClin 300, and < 0.1% sodium azide.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Triage BNP Test for the Beckman Coulter Immunoassay Systems

   Biosite Triage BNP Test

2. Predicate 510(k) number(s):

   k033383

   k051787

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Assay principle	Two site immunoenzymatic (sandwich) assay	Same
Sample type	EDTA plasma	Same

Differences		
Item	Device	Predicate
Indications for Use	for the in vitro quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to heart failure). The test is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.	for the in vitro quantitative measurement of B-Type Natriuretic Peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure). The test is also used for the risk stratification of patients with acute coronary syndromes.

K. Standard/Guidance Document Referenced (if applicable):

CLSI H18-A2, CLSI EP5-A

L. Test Principle:

The Triage BNP test is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-human BNP antibody-alkaline phosphatase conjugate and paramagnetic particles coated with mouse omniclonal anti-human BNP antibody. BNP in human plasma binds to the immobilized anti-BNP on the solid phase, while the mouse anti-BNP conjugate reacts specifically with bound BNP. After incubation in a reaction vessel, separation in a magnetic field and washing, remove materials not bound to the solid phase. A chemiluminescent substrate, Lumi-Phos 530, is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of BNP in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Previously demonstrated for k033383. The data/information is included in the labeling.

   b. *Linearity/assay reportable range:*

      Previously demonstrated for k033383. The data/information is included in the labeling.

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

      Previously demonstrated for k033383. The data/information is included in the labeling.

   d. *Detection limit:*

      Previously demonstrated for k033383. The data/information is included in the labeling.

   e. *Analytical specificity:*

      Previously demonstrated for k033383. The data/information is included in the labeling.

f. *Assay cut-off:*

BNP results less than or equal to 100 pg/mL are representative of normal values in patients without CHF. BNP results greater than 100 pg/mL are considered abnormal and suggestive of patients with CHF.

2. Comparison studies:

a. *Method comparison with predicate device:*
Previously demonstrated in comparison to Triage BNP test (k021317, k051787) – refer to k033383. A comparison of 412 EDTA plasma samples measured values using the Triage® BNP test on the Access Immunoassay System and the Triage BNP test gave the following statistical data using the Passing- Bablock regression analysis: n = 412, range of observations = 5 – 4970 pg/mL, slope = 1.00, r = 0.95, intercept = - 0.15. This device is identical to the predicate device (k033383) except for a modification to the Indications for Use.

b. *Matrix comparison:*

EDTA plasma is the only sample type indicated.

3. Clinical studies:

a. *Clinical Sensitivity:*

Previously demonstrated for k033383. The data/information is included in the labeling.

b. *Clinical specificity:*

Previously demonstrated for k033383. The data/information is included in the labeling.

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

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. The Triage BNP Test for the Beckman Coulter Immunoassay Systems correlates with (see Method Comparison section) and is identical to the Biosite Triage BNP Test in principle, reagents and procedure.

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 k033383. The data/information is included in the labeling.

5. Expected values/Reference range:

   Previously demonstrated for k033383. The data/information is included in the labeling.

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.