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

A. 510(k) Number:

k051787

B. Purpose for Submission:

Modification to the Triage® BNP Test to expand the Indications for Use of the Biosite Triage BNP Test, as an aid in the risk stratification of patients with heart failure.

C. Measurand:

BNP (B-Type Natriuretic Peptide)

D. Type of Test:

Quantitative Fluorescent Immunoassay

E. Applicant:

Biosite Incorporated

F. Proprietary and Established Names:

Triage® BNP Test

G. Regulatory Information:

1. <u>Regulation section:</u>

    21 CFR section 862.1117, B-type natriuretic peptide test system

2. <u>Classification:</u>

    Class II

3. <u>Product code:</u>

    NBC, test,natriuretic peptide

4. <u>Panel:</u>

75, Chemistry

H. Intended Use:

1. Intended use(s):

   The BNP test system is an in vitro diagnostic device intended to measure BNP in whole blood and plasma.

2. Indication(s) for use:

   The Triage BNP Test is a rapid, point of care fluorescence immunoassay to be used with the Triage Meter or Triage MeterPlus for the quantitative measurement of B-Type Natriuretic Peptide (BNP) in EDTA anti-coagulated whole blood or plasma specimens. The test is intended to be used as an aid in the:

   - Diagnosis of heart failure
   - Assessment of heart failure severity
   - Risk stratification of patients with acute coronary syndromes
   - Risk stratification of patients with heart failure

3. Special conditions for use statement(s):

   The device is for prescription use.

4. Special instrument requirements:

   Triage Meter or Triage MeterPlus

I. Device Description:

The Triage BNP Test is a ready-to-use, single use device. All reagents necessary to run the test are contained within the device. The device contains anti-BNP monoclonal antibodies (mouse) and anti-BNP polyclonal antibodies labeled with a fluorescent dye and immobilizied on a solid phase and stabilizers.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Triage® BNP Test

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

   de novo classified as Class II (k003475)

Device modifications cleared under k021317 and k032235

3. Comparison with predicate:

Similarities		
Item	Triage BNP k051787	Predicate: Triage BNP k021317
Test principle, procedure and reagents	same	same

Differences		
Item	Triage BNP k051787	Predicate: Triage BNP k021317
Indications for use	Diagnosis of heart failure, Assessment of heart failure severity, Risk stratification of patients with acute coronary syndromes, risk stratification of patients with heart failure	Diagnosis of heart failure, Assessment of heart failure severity, Risk stratification of patients with acute coronary syndromes

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

Not applicable

L. Test Principle:

The Triage BNP Test is a single-use fluorescence immunoassay designed to determine the concentration of BNP EDTA-anticoagulated whole blood or plasma specimens. The specimen is added to the sample port of the test device with a transfer pipette that is designed to deliver the appropriate amount of sample. After the specimen is added, the device is inserted into the Triage Meter. The meter is programmed to automatically perform the BNP analysis after the sample has reacted with the reagents within the BNP device. The reaction and analysis time take about 15 minutes. The BNP measurement is based on the amount of fluorescence the meter detects within the measurement zone of the device. A greater amount of fluorescence detected by the meter indicates a higher amount of BNP in the specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Previously demonstrated for k021317 and k032235. The data/information is

included in the labeling.

b. *Linearity/assay reportable range:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

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

Previously demonstrated for k021317 and k032235.

d. *Detection limit:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

e. *Analytical specificity:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

f. *Assay cut-off:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

2. Comparison studies:

a. *Method comparison with predicate device:*

Previously reviewed under k003475.

b. *Matrix comparison:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling

3. Clinical studies:

a. *Clinical Sensitivity:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

b. *Clinical specificity:*

Previously demonstrated for k021317 and k032235. The data/information is included in the labeling.

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

In support of the new 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 various 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 k021317 and k032235. The data/information is included in the labeling.

5. Expected values/Reference range:

Previously demonstrated for k021317 and k032235. 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.