

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k072892

**B. Purpose for Submission:**

New devices: Triage® Total Controls 5 and Triage® Total Calibration Verification 5

**C. Measurand:**

Control and calibrator verification material for test systems containing CK-MB, Myoglobin, Troponin I,  $\beta$ -type natriuretic peptide (BNP), and D-Dimer

**D. Type of Test:**

Control materials

**E. Applicant:**

Biosite Incorporated

**F. Proprietary and Established Names:**

Triage® Total Controls 5

Triage® Total Calibration Verification 5

**G. Regulatory Information:**

1. Regulation section:

21 CFR§862.1660

2. Classification:

Class I, reserved

3. Product code:

JJY

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See indication for use

2. Indication(s) for use:

The Triage® Total Controls 5 are assayed materials to be used with the Triage® Profiler S.O.B.™ Panel, Triage® CardioProfilER® Panel, Triage Cardiac Panel, Triage® BNP Test, Triage® D-Dimer Test and the Triage Meters to assist in monitoring test performance.

The Triage® Total Calibration Verification 5 are assayed materials to be used with the Triage® Profiler S.O.B.™ Panel, Triage CardioProfilER® Panel, Triage® Cardiac Panel, Triage® BNP Test, Triage® D-Dimer Test and the Triage Meters to verify the calibration of the Test Devices throughout the measurable range.

3. Special conditions for use statement(s):

Prescription Use

4. Special instrument requirements:

Triage MeterPlus® and Triage MeterPro®

**I. Device Description:**

The Triage® Total Control 5 Controls 1 and 2, and the Triage® Total Calibration Verification 5 Levels A, B, C, D, E are single-use 0.29 mL unit dose quality control materials prepared with concentrated purified CK-MB, myoglobin, troponin I, BNP and D-Dimer and human EDTA plasma at defined levels. The human plasma material has been tested for hepatitis B surface antigen, antibodies to hepatitis C, and antibodies against human immunodeficiency virus. The controls are stored frozen at < -20°C. Preservatives and stabilizers are added to maintain product integrity.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

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

Triage® Profiler S.O.B. Calibration Verification Controls

2. Predicate K number(s):

k040459

3. Comparison with predicate:

<b>Similarities-Triage® Total Controls 5</b>		
Item	Device	Predicate
Intended use	The Triage Total Controls are assayed materials to be used with the Triage Profiler S.O.B. Panel, Triage CardioProfiler Panel, Triage Cardiac Panel, Triage BNP Test, Triage D-Dimer Test and the Triage Meters to assist in monitoring test performance.	Same
Form	Liquid	Same
Analytes	CK-MB, myoglobin, Troponin I, BNP, D-Dimer	Same
Storage (unopened)	≤ -20°C	Same
Matrix	EDTA Human Plasma	Same
Room Temp claim	30 minutes	Same
Levels	2	Same

<b>Differences - Triage® Total Controls 5</b>		
Item	Device	Predicate
Packaging	0.29 mL polystyrene unit-dose vial	3.0 mL polypropylene vial

<b>Similarities - Triage® Total Calibration Verification 5</b>		
Item	Device	Predicate
Intended Use	The Triage Total Calibration Verification 5 materials are to be used with the Triage Profiler S.O.B. Panel, Triage CardioProfiler Panel, Triage Cardiac Panel, Triage BNP Test, Triage D-Dimer Test and Triage Meters to verify the calibration of the Test Devices throughout the measurable range.	Same
Form	Liquid	Same
Analytes	CK-MB, myoglobin, Troponin I, BNP, D-Dimer	Same
Storage (unopened)	≤ -20°C	Same
Matrix	EDTA Human Plasma	Same
Room Temp claim	30 minutes	Same
Levels	5	Same

Differences - Triage® Total Calibration Verification 5		
Item	Device	Predicate
Packaging	0.29 mL polystyrene unit-dose vial	3.0 mL polypropylene vial

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

No standard/guidance documents were referenced.

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability

The materials are traceable to in-house purified, and analyzed antigens.

Stability

Closed vial stability was performed at  $\leq -20^{\circ}\text{C}$ . The devices are single use products. Recovery at all time points tested was within sponsor's acceptance criteria of 80-120%.

Expected values

Values assigned to the controls are obtained from multiple runs of Triage® Total Calibration Verification 5 and Triage® Total Controls 5 on multiple device lots over several days.

d. *Detection limit:*

Not applicable

