B. 510(k) Summary of Safety and Effectiveness

Triage® Total Controls 5 / Triage® Total Calibration Verification 5

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072892

1. Name and Address of Submitter

DEC 07 2007

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
Telephone:	(858) 805-2722
Telefax:	(858) 586-7543
Contact Person:	Fil V. Buenviaje Sr. Manager, Regulatory Compliance
Date Summary Prepared:	October 5, 2007

2. Device Name and Classification

Trade Name:	Triage® Total Controls 5 Triage® Total Calibration Verification 5
Common Name:	Not Applicable
Classification of Device:	21 CFR 862.1660, Quality Control Material (Assayed and Unassayed) Product Code: JJY

3. Predicate Devices

K040459 – Triage® Profiler S.O.B. (Shortness of Breath) Controls and the Triage® Profiler S.O.B. Calibration Verification Controls

4. Device Description

The Triage Total Controls 5 Control 1 and 2, and 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 controls are stored frozen at < -20°C. Preservatives and stabilizers are added to maintain product

integrity. The quality control materials are not calibrators and are not used to calibrate the Triage Test Devices.

5. Intended 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 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 the Triage Meters to verify the calibration of the Test Devices throughout the measurable range.

6. Product Performance

The stability of the Triage Total Controls 5 and the Triage Total Calibration Verification 5 have been validated according to established procedures at the manufacturing site. The performance of the control materials are similar to other products in commercial distribution intended for similar use.

7. Comparison to Predicate Device

The Triage Total Controls 5 and Triage Total Calibration Verification 5 employ similar characteristics to the predicate device including multi-analytes assay control, 5 levels, liquid control, EDTA human plasma matrix and ≤ -20°C storage condition.

8. Conclusion

The information presented in this Premarket Notification demonstrates the suitability of the device for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution. Further, the information presented herein indicate that the Triage Total Controls 5 and the Triage Total Calibration Verification 5 are substantially equivalent in intended use and performance to the Triage Profiler S.O.B. Controls and the Triage Profiler S.O.B. Calibration Verification Controls thereby, supporting 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 07 2007

BioSite, Inc.
c/o Mr. Fil V. Buenviaje
Sr. Manager, Regulatory Compliance
9975 Summers Ridge Road
San Diego, CA 92121

Re: K072892
Trade Name: Triage® Total Controls 5, Triage® Total Calibrator Verification 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: October 5, 2007
Received: October 16, 2007

Dear Mr. Buenviaje:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072892

Device Name: **Triage® Total Controls 5**
Triage® Total Calibration Verification 5

Indications 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 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 the Triage Meters to verify the calibration of the Test Devices throughout the measurable range.

Prescription Use X AND/OR Over-The Counter Use
(Per 21 CFR 801.109) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072892