510(k) Summary of Safety and Effectiveness

JUN - 6 2008

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

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

510(k) number is: K080269

1. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
Telephone:	(858) 805-2154
Telefax:	(858) 695-7100
Contact Person:	Dawn A. Allenby, Esq. Manager, Regulatory Affairs
Date Summary Prepared:	June 2, 2008

2. Device Name and Classification

Trade Name:	Triage CardioProfilER Panel
Common Name:	CardioProfilER Panel
Classification of Device:	21 CFR 862.1117, B-type natriuretic peptide test system Product Code: NBC
	21 CFR 862.1215, Fluorometric Method, CPK or Isoenzymes Product Code: JHX
	21 CFR 866.5680, Myoglobin, Antigen, Antiserum, Control Product Code: DDR
	21 CFR 862.1215, Immunoassay Method, Troponin Subunit Product Code: MMI

Trade Name:	Triage Profiler S.O.B. Panel
Common Name:	Profiler S.O.B. Panel
Classification of Device:	21 CFR 862.1117, B-type natriuretic peptide test system Product Code: NBC 21 CFR 862.1215, Fluorometric Method, CPK or Isoenzymes Product Code: JHX 21 CFR 866.5680, Myoglobin, Antigen, Antiserum, Control Product Code: DDR 21 CFR 862.1215, Immunoassay Method, Troponin Subunit Product Code: MMI 21 CFR 864.7320, Fibrinogen/Fibrin Degradation Products Assay Product Code: DAP

3. Predicate Device

Biosite Triage BNP Test (K051787)

4. Device Description and Intended Use

The Triage CardioProfilER 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.

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), an aid in 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 an aid in the risk stratification of patients with acute coronary syndromes.

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 against 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 Profiler S.O.B. 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 Test Cartridges are inserted into the Triage Meter and results for each analyte are measured and displayed on the display screen or printout. Internal assay controls (positive and negative controls) and automatic endpoint detection technology is used to indicate assay completion.

5. Comparison to Predicate Device

The devices and test methods described in this Premarket Notification for the Triage CardioProfilER Panel and the Profiler S.O.B. Panel are identical in principle, reagents and procedure to their predecessors. More specifically, the BNP assays included in these panels are identical to the BNP assay used in the Triage BNP Test (K051787). Moreover, the Triage BNP Test serves as the predicate method for the use of a circulating biomarker to provide prognostic information in patients with heart failure. Therefore, the use of the Triage CardioProfilER and the Profiler S.O.B. Panels as an aid in the risk stratification of patients with heart failure is substantially equivalent to the predicate method.

6. Conclusion

The information presented in this Premarket Notification demonstrates the substantial equivalence of the intended use claims of the Triage CardioProfilER Panel and the Triage Profiler S.O.B. Panel to the intended use claims of the Triage BNP Test (K051787) which has been reviewed and cleared through the 510(k) Premarket Notification process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2008

Biosite Incorporated
c/o Ms. Dawn A. Allenby, Esq.
Manager, Regulatory Affairs
9975 Summers Ridge Road
San Diego, CA 92121

Re: k080269
Trade/Device Name: Triage® Profiler S.O.B.™ (Shortness of Breath Panel), Triage® CardioProfiler® Panel
Regulation Number: 21 CFR§ 862.1117
Regulation Name: B-Type Natriuretic Peptide Test System
Regulatory Class: Class II
Product Code: NBC, JHX, DDR, MMI, DAP
Dated: January 31, 2008
Received: March 19, 2008

Dear Ms. Allenby:

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 application (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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and 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): **K080269**

Device Name: **Triage® Profiler S.O.B.™ (Shortness of Breath) Panel**

Indications 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.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K080269

Indications for Use

510(k) Number (if known): **K080269**

Device Name: **Triage® CardioProfilER® Panel**

Indications for Use:

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), an aid in 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 an aid in the risk stratification of patients with acute coronary syndromes.

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