510(k) Summary of Safety and Effectiveness K030286

Triage® Cardio ProfilER / Triage® Cardiac Panel FEB 21 2003

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: **(To be determined)**

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	1/27/03

B. Device Names

1. Trade Name

   Triage® Cardio ProfilER / Triage® Cardiac Panel

2. Common / Usual Name

   Triage® Cardio ProfilER / Triage® Cardiac Panel

3. Classification Name

   Fluorometric Method, CPK or Isoenzymes (862.1215)
   Product Code JHX

   Immunoassay Method, Troponin Subunit (862.1215)
   Product Code MMI

   Myoglobin, Antigen, Antiserum, Control (866.5680)
   Product Code DDR

   Test, Natriuretic Peptide (862.1117) (Triage® Cardio ProfilER)
   Product Code NBC

C. Predicate Devices

Triage® Cardiac Panel (K973126)

Triage® BNP Test (K021317)

D. Device Description and Intended Use

The Triage® Cardio ProfilER is a fluorescence immunoassay to be used with the Triage® Meter 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), the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), and the risk stratification of patients with acute coronary syndromes.

The Triage® Cardiac Panel is a fluorescence immunoassay to be used with the Triage® Meter for the quantitative determination of Creatine Kinase MB, myoglobin and troponin I in EDTA whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury).

E. Summary of Comparison Data

The Triage® Cardio ProfilER is a combination of the two predicate devices. The only differences between the Triage® Cardio ProfilER and the predicate devices is that the Triage® Cardio uses EDTA as an anticoagulant, while the Triage® Cardiac Panel uses heparin as an anticoagulant, and the troponin assay has a lower analytical sensitivity than the troponin assay on the Triage® Cardiac Panel. The only difference between the modified Triage® Cardiac Panel and the Triage® Cardio ProfilER is the absense of a BNP assay on the Triage® Cardiac Panel.

F. Conclusion

The design control process led to a determination that the Triage® Cardio ProfilER and Triage® Cardiac Panel are substantially equivalent to the previously cleared predicate devices. The evaluation has led to assurance that the Triage® Cardio ProfilER and Triage® Cardiac Panel are safe and effective for their intended uses and no new issues of safety and effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 21 2003

Jeffery R. Dahlen, Ph.D.
Principal Scientist
Clinical & Regulatory Affairs
Biosite® Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k030286
Trade/Device Name: Triage® Cardio ProfilER/Triage® Cardiac Panel
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: NBC; JHX; MMI; DDR
Dated: January 27, 2003
Received: January 28, 2003

Dear Dr. Dahlen:

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): (to be determined) K030286

Device Name: Triage® Cardio ProfilER / Triage® Cardiac Panel

Indications For Use:

The Triage® Cardio ProfilER is a fluorescence immunoassay to be used with the Triage® Meter 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), the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), and the risk stratification of patients with acute coronary syndromes.

The Triage® Cardiac Panel is a fluorescence immunoassay to be used with the Triage® Meter for the quantitative determination of Creatine Kinase MB, myoglobin and troponin I in EDTA whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030286

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)