JAN 2 3 2006

K052789

II. 510(k) Summary of Safety and Effectiveness

In accordance with the provisions of Section 4 of the Safe Medical Devices Act of 1990 and 21 CFR 807.92, the following summary is provided. Biosite requests that this document be maintained CONFIDENTIAL until such time that the product is cleared by the Food and Drug Administration via the 510(k) process and in accordance with the provisions of the Act.

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
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Contact Person:	Rachael S. Williamson, MS, RAC
Date Summary Prepared:	January 4, 2006

B. Product

Triage® BNP Test for the Beckman Coulter Immunoassay Systems

C. Predicate Devices

Biosite Triage BNP Test for the Beckman Coulter Immunoassay Systems (K033383)
Biosite Triage BNP Test (K021317 and K051787)

D. Device Description and Intended Use

The Triage BNP test is intended for use with Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725 and UniCel Dxl 800) for the *In Vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure). The test also is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.

E. Summary of Substantial Equivalence

Various peer-reviewed publications have described the utility of BNP measurements as an aid in the risk stratification of patients with heart failure. Higher BNP concentrations or the lack of a decrease in the BNP concentration from hospital admission to discharge indicate an increased risk of hospitalization or death in patients with heart failure.

The device and test method described in this Premarket Notification is identical in principle, reagents and procedure to its predecessor, the currently marketed Triage BNP Test for the Beckman Coulter Immunoassay (K033383).

Moreover, the Triage BNP Test (K051787) serves as the predicate method for the use of a circulating biomarker to provide prognostic information in patients with heart failure. The use of the Triage BNP Test for the Beckman Coulter Immunoassay Systems as an aid in the risk stratification of patients with heart failure is substantially equivalent to the predicate method.

F. Conclusion

In conclusion, the data presented in this Premarket Notification demonstrate the substantial equivalence of the Triage BNP Test for the Beckman Coulter Immunoassay Systems to currently marketed devices which have been reviewed and cleared through the 510(k) Premarket Notification process. Such data are a critical element in establishing the fundamental safety and effectiveness of the device and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 3 2006

Ms. Rachael Williamson
Regulatory Affairs Specialist
Biosite Incorporated
9975 Summers Ridge Road
San Diego, CA 92121

Re: k052789
Trade/Device Name: Triage BNP Test for the Beckman Coulter Immunoassay Systems
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC
Dated: September 30, 2005
Received: October 31, 2005

Dear Ms. Williamson

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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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): k052789

Device Name: **Triage BNP Test for the Beckman Coulter Immunoassay Systems**

Indications For Use:

The Triage BNP test is intended for use with Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725 and UniCel Dxl 800) for the *In Vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure). The test also is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.

Prescription Use ✓ 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)

Ann Chaplie
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k052789