

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
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	September 17, 2005

B. Product

Triage[®] BNP Test

C. Predicate Devices

Biosite Triage BNP Test (K021317)
Roche Elecsys ProBNP Immunoassay (K032646)

D. Device Description and Intended Use

The Triage BNP Test is a rapid, point of care fluorescence immunoassay to be used with the Triage Meters for the quantitative measurement of B-Type Natriuretic Peptide (BNP) in EDTA anticoagulated whole blood or plasma specimens. 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 the currently marketed Triage BNP Test (K021317).

The Elecsys ProBNP Immunoassay (K032646) is used as a predicate method for the use of a circulating biomarker to provide prognostic information in patients with heart failure. Although the test measures a different analyte, i.e. NT-proBNP, the use of the Triage BNP Test 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 to predicate methods.



SEP 22 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jeffrey Dahlen, Ph.D.
Director, Clinical & Regulatory Affairs
Biosite Incorporated
11030 Roselle Street
San Diego, CA 92121

Re: k051787
Trade/Device Name: Triage BNP Test
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC
Dated: June 30, 2005
Received: July 1, 2005

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.

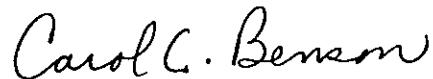
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,



Carol C. Benson, M.A.
Acting 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): K051787

Device Name: Triage BNP Test

Indications For Use:

The Triage® BNP Test is a rapid, point of care fluorescence immunoassay to be used with the Triage Meter or Triage MeterPlus for the quantitative measurement of B-Type Natriuretic Peptide (BNP) in EDTA anticoagulated whole blood or plasma specimens. The test is intended to be used as an aid in the:

- Diagnosis of heart failure
- Assessment of heart failure severity of
- Risk stratification of patients with acute coronary syndromes
- Risk stratification of patients with heart failure

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)

[Signature]
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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