K032235

JAN 2 8 2004

Biosite Incorporated
Triage® B-Type Natriuretic Peptide (BNP) Test

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: January 13, 2003

Submitter: Biosite Incorporated

Address: 11030 Roselle Street
San Diego, CA 92121
Phone (858) 455-4808
Fax (858) 535-8350

Contact: Jeffrey R. Dahlen, Ph.D.
Clinical & Regulatory Affairs
Principal Scientist

Device: Trade/Proprietary Name:
Triage® B-Type Natriuretic Peptide (BNP) Test

Common/Usual Name:
BNP Test

Classification: Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
Panel – Clinical Chemistry and Toxicology
Classification Code – NBC

Predicate Devices: Triage® B-Type Natriuretic Peptide (BNP) Test

Device Description and Intended Use:

The Triage® BNP Test is intended for use with the Triage® Meter for the rapid *in vitro* quantitative measurement of B-Type Natriuretic Peptide (BNP) in human capillary whole blood, venous whole blood or plasma specimens using EDTA as the anticoagulant. The test is 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.

Assessment of Performance:

A comparison between Triage® BNP Test results obtained from capillary whole blood specimens and venous whole blood specimens from the same individual was performed. A total of 67 paired samples were evaluated. All results were blinded.

43.3% of the capillary blood samples were obtained using a single finger stick, 35.8% of the samples were obtained using two finger sticks, and 20.9% of the samples were obtained using three or more finger sticks. Data were analyzed by linear regression and potential differences in the data sets were evaluated using the Wilcoxon Signed Ranks test, with $p < 0.05$ indicating a significant difference in the data sets. Analyses were performed based on the number of fingersticks required to obtain enough sample, and the entire data set was analyzed. The results of the analyses indicate that capillary whole blood is a suitable sample for use with the Triage® BNP Test and is equivalent to results obtained from venous whole blood. Results obtained from capillary whole blood were not significantly different from results obtained using venous whole blood. The correlation was not influenced by the number of fingersticks needed to collect enough sample to run the test.

Imprecision studies using whole blood samples spiked with purified BNP indicated that the test imprecision using whole blood is comparable to the imprecision using EDTA-anticoagulated plasma

Conclusion:

The results of the study indicate that capillary whole blood is a suitable sample for use with the Triage® BNP Test and is equivalent to results obtained from venous whole blood.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 8 2004

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

Re: k032235
Trade/Device Name: Triage® B-Type Natriuretic Peptide (BNP) Test
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC
Dated: November 25, 2003
Received: November 26, 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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

510(k) Number (if known): K032235

Device Name: Triage® B-Type Natriuretic Peptide (BNP) Test

Indications for Use: The Triage® BNP Test is intended for use with the Triage® Meter for the rapid *in vitro* quantitative measurement of B-Type Natriuretic (BNP) in human capillary whole blood, venous whole blood or plasma specimens using EDTA as the anticoagulant. The test is 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032235

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