

DEC 23 2003

510(k) Summary

Triage® B-Type Natriuretic Peptide (BNP) Test for the Beckman Coulter Immunoassay Systems

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

510(k) Number: K033383

Name and Address of Submitter

Company Name: Biosite Incorporated
Address: 11030 Roselle Street
San Diego, CA 92121
Telephone: (858) 455-4808
Fax: (858) 535-8350
Contact Person: Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared: 12/19/03

Device Names

1. Trade Name

Triage B-Type Natriuretic Peptide (BNP) Test for the Beckman Coulter Immunoassay Systems

2. Common / Usual Name

BNP Test

3. Classification Name

B-Type Natriuretic Peptide Test System

Device Description and Intended Use

The Triage BNP test for the Beckman Coulter Immunoassay Systems reagents consist of reagent packs, calibrators, QC, substrate and wash buffer. The test uses the same antibodies and calibrators traceable to the same BNP gold standard as the previously cleared Biosite Triage BNP Test.

The Triage BNP test is intended for use with the Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725, and UniCel DxI 800) for the rapid in vitro quantitative measurement of B-Type Natriuretic Peptide (BNP) in 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.

Comparison to Predicate Method

A method comparison was performed using 412 EDTA plasma samples with BNP concentrations throughout the measurable range of the test. A Passing-Bablok regression analysis of the Triage BNP test for the Beckman Coulter Immunoassay Systems versus the predicate Biosite Triage BNP test described a linear relationship with a slope of 1.00, intercept of -0.15 and a correlation coefficient of 0.95. Furthermore, applying a cutoff of 100 pg/mL yielded 96.1% accuracy between the two methods. The analytical performance characteristics are equivalent to the predicate method, as well as other Beckman Coulter Immunoassay System tests.

Conclusion

The Triage BNP test for the Beckman Coulter Immunoassay Systems is substantially equivalent to the predicate method. The results from comparison studies, coupled with the fact that the test uses the same antibodies as the predicate method indicate that Triage BNP results can be used interchangeably.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 2003

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

Re: k033383
Trade/Device Name: Triage[®] B-Type Natriuretic Peptide (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; JIT; JJX
Dated: October 22, 2003
Received: October 24, 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).

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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 (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 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): K033383

Device Name: Triage® B-Type Natriuretic Peptide (BNP) Test for the Beckman Coulter Immunoassay Systems

Indications For Use:

The Triage® BNP test is intended for use with the Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725, and UniCel DxI 800) for the in vitro quantitative measurement of B-Type Natriuretic Peptide (BNP) in 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. 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
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K033383

Prescription Use OR
(Per 21 CFR 801.109)

Over-The Counter Use