JUL 1 2002

510(k) Summary

Triage® B-Type Natriuretic Peptide (BNP) Test

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

510(k) Number: **K021317**

Name and Address of Submitter

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Date Summary Prepared:	6/28/02

Device Names

1. Trade Name

   Triage® B-Type Natriuretic Peptide (BNP) Test

2. Common / Usual Name

   BNP Test

3. Classification Name

   B-Type Natriuretic Peptide Test System

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 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. The test also is used for the risk stratification of patients with acute coronary syndromes.

Summary of Clinical Data

BNP concentrations measured in patients with acute coronary syndromes (ACS) or cardiovascular disease provide prognostic information about the patient's risk for death and the development of CHF. Statistically significant increases in death, future myocardial infarction, and CHF have been associated with higher BNP concentrations measured within the first 72 hours after the onset of ACS symptoms. In a recent clinical study, BNP concentrations were evaluated in an observational, retrospective manner in patients with ACS (consisting of unstable angina, myocardial infarction with ST-segment elevation, or myocardial infarction without ST-segment elevation). BNP measurements were performed on specimens obtained within 72 hours after the onset of ischemic discomfort from a population of 2525 high-risk ACS patients that met standard diagnostic criteria for ACS. Patients whose BNP concentration was at least 80 pg/mL had higher rates of death, myocardial infarction, and CHF both at 30 days and at 10 months after presentation than patients whose BNP concentration was below 80 pg/mL. In this population of patients with ACS, BNP measurements within the first 72 hours after the onset of symptoms provide useful predictive information to aid in the risk stratification of patients with ACS.

Comparison to Predicate Methods

The device and test method described in the labeling are identical to the predicate device, the Triage® BNP Test. The antibodies used in the microplate assays and the Triage® BNP Test are identical, and both platforms utilize a sandwich ELISA assay. Furthermore, the same reagents used to calibrate the Triage® BNP Test also were used to calibrate the microplate assays. In this regard, the two assay formats are substantially equivalent.

The Dade Stratus Cardiac Troponin-I and Dade Dimension RxL Cardiac Troponin-I are used as predicate methods for the conceptual description of how a biochemical marker can be used to provide prognostic information to a physician. Although these predicate methods describe a different analyte, the description of how the test results should be interpreted with respect to the prognosis of the patient are substantially equivalent.

Conclusion

The use of the Triage® BNP Test to aid in the risk stratification of patients with ACS is substantially equivalent to the predicate methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 1 2002

Jeffery Dahlen, Ph.D.
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Clinical Regulatory Affairs
Biosite, Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k021317
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: April 24, 2002
Received: April 25, 2002

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021317

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

Indications For Use:

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021317

(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)