B. 510(k) Summary of Safety and Effectiveness

JAN 2 9 2007

Triage® Protein C Test

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

The assigned 510(k) number is: **K062530**

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:	Fil V. Buenviaje Manager, Regulatory Compliance
Date Summary Prepared:	January 17, 2007

B. Device Name and Classification

Trade Name:	Triage® Protein C Test
Common Name:	Protein C
Classification of Device:	21 CFR 864.7290, Factor Deficiency Test Product Code: GGP

C. Predicate Device

Asserachrom® Protein C Kit (K854016)

D. Device Description

The Triage Protein C Test is a single-use device containing murine monoclonal antibodies against Protein C labeled with a fluorescent dye and purified Protein C antigen immobilized on the solid phase, and stabilizers. Additionally, there are built-in control features that ensure that the test was performed properly and the reagents were functionally active.

The Test Cartridge is inserted into the Triage Meter and results are measured and displayed on the display screen or printout in approximately 15 minutes. Internal assay controls (positive and negative controls) and automatic endpoint detection technology is used to indicate assay completion.

E. Device Intended Use

The Triage Protein C Test is a rapid, point-of-care fluorescence immunoassay to be used with the Triage Meters for the rapid, quantitative determination of Protein C in citrated whole blood or plasma specimens in patients with signs and symptoms of sepsis. The test is not intended for use in patients with vitamin K deficiency, DIC, cancers, HIV and liver and renal diseases as these disease conditions have not been evaluated.

F. Comparison to Predicate Device

The performance of the Triage Protein C Test was established using samples collected from patients who presented with suspected or proven infection, evidence of systemic inflammation and at least one sepsis-induced organ failure who were enrolled in a previous clinical investigation. Two hundred twenty-five split patient samples were run in the Triage Protein C Test and a predicate method for the purpose of determining if the two methods yield similar results. Testing was conducted at three independent clinical laboratory sites in accordance with NCCLS Evaluation Protocol EP9-A2, Vol. 22, No. 19, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition.

G. Conclusion

The information presented in this Premarket Notification demonstrates that the performance of the Triage Protein C Test for use with citrated human blood and plasma is substantially equivalent to the predicate device.

Equivalence was demonstrated using manufactured reagents along with patient and quality control samples with measured Protein C values spanning the reportable range of the assay.

These studies demonstrate the substantial equivalence of the Triage Protein C Test to existing products already marketed for the quantitative determination of Protein C. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

BIOSITE Incorporated
C/O Fil V. Buenviaje
9975 Summers Ridge Road
San Diego, California 92121

Re: k062530
Trade/Device Name: Triage Protein C Test
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: August 28, 2006
Received: August 29, 2006

JAN 2 9 2007

Dear Mr. Buenviaje
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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use

510(k) Number (if known): **K062530**

Device Name: **Triage® Protein C Test**

Indications for Use:

The Triage Protein C Test is a rapid, point-of-care fluorescence immunoassay to be used with the Triage Meters for the rapid, quantitative determination of Protein C in citrated whole blood or plasma specimens in patients with signs and symptoms of sepsis. The test is not intended for use in patients with vitamin K deficiency, DIC, cancers, HIV and liver and renal diseases as these disease conditions have not been evaluated.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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