JUN 29 2005

510(k) Summary of Safety and Effectiveness

Triage D-Dimer Calibration Verification Controls / Triage D-Dimer Controls

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

510(k) Number: **k050799**

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8344
Contact Person:	Rachael S. Williamson
Date Summary Prepared:	6/22/05

B. Device Names

1. Trade Name

   Triage D-Dimer Calibration Verification Controls / Triage D-Dimer Controls

2. Common / Usual Name

   Not Applicable

3. Classification Name

   Plasma, Coagulation Control
   21 CFR 864.5425
   Class II
   Product Code: GGN

C. Predicate Devices

Bio-Rad Liquichek™ D-dimer Control Levels 1, 2 and 3 (k032017)

D. Device Description and Intended Use

The Triage D-Dimer Calibration Verification Controls are to be used with the Triage D-Dimer Test and Triage MeterPlus to verify the calibration of the Triage D-Dimer Test throughout the measurable range.

The Triage D-Dimer Controls are assayed materials to be used with the Triage D-Dimer Test and Triage MeterPlus to assist the laboratory in monitoring test performance.

E. Conclusion

The information provided in the premarket notification demonstrates that the Triage D-Dimer Calibration Verification Controls / Triage D-Dimer Controls are substantially equivalent to previously approved predicate devices. The information provided assures

that the Triage D-Dimer Calibration Verification Controls / Triage D-Dimer Controls are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 2005

Ms. Rachael S. Williamson
Regulatory Affairs Specialist
Biosite Incorporated
11030 Roselle Street
San Diego, California 92121

Re: k050799
Trade/Device Name: Triage D-Dimer Calibration Verification Controls and Triage D-Dimer Controls
Regulation Number: 21 CFR § 864.5425
Regulation Name: Plasma coagulation control
Regulatory Class: II
Product Code: GGN
Dated: May 17, 2005
Received: May 18, 2005

Dear Ms. Williamson:

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 (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,

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

Enclosure

Indications for Use

510(k) Number (if known): K050799

Device Name: Triage® D-Dimer Test

Indications For Use:

The Triage D-Dimer Calibration Verification Controls are to be used with the Triage D-Dimer Test and Triage MeterPlus to verify the calibration of the Triage D-Dimer Test throughout the measurable range.

The Triage D-Dimer Controls are assayed materials to be used with the Triage D-Dimer Test and Triage MeterPlus to assist the laboratory in monitoring test performance.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)
Division of Clinical Laboratory Devices
510(k) Number K050799