JAN 2 3 2003

510(k) Summary of Safety and Effectiveness

Triage® Cardio ProfilER / Triage® Cardiac Controls K030089

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: **(To be determined)**

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8350
Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	1/7/03

B. Device Names

1. Trade Name

   Triage® Cardio ProfilER / Triage® Cardiac Controls

2. Common / Usual Name

   Not Applicable

3. Classification Name

   Quality Control Material (Assayed and Unassayed)
   21 CFR 862:1660
   Class I
   Product Code: JJY

C. Predicate Devices

Triage® Cardiac Controls (K974461)
Triage® BNP Controls (K000230)

D. Device Description and Intended Use

The Triage® Cardio ProfilER / Triage® Cardiac Controls are to be used with the Triage® Cardio ProfilER / Triage® Cardiac Panel and Triage® Meter to assist the laboratory in monitoring test performance.

E. Summary of Comparison Data

The Triage® Cardio ProfilER / Triage® Cardiac Controls are a combination of the two predicate devices. The only difference between the Triage® Cardio ProfilER / Triage® Cardiac Controls and the predicate devices is that the Triage® Cardio ProfilER / Triage® Cardiac Controls are prepared in a matrix that contains EDTA, while the Triage® Cardiac Controls are prepared in a matrix that contains heparin.

F. Conclusion

The information provided in the premarket notification demonstrates that the Triage® Cardio ProfilER / Triage® Cardiac Controls are substantially equivalent to previously approved predicate devices. The information provided assures that the Triage® Cardio ProfilER / Triage® Cardiac Controls are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 23 2003

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

Re: k030089
Trade/Device Name: Triage® Cardio ProfilER / Triage® Cardiac Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed).
Regulatory Class: Class I
Product Code: JJY
Dated: January 7, 2003
Received: January 10, 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). 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 I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K030089

510(k) Number (if known): (to be determined)

Device Name: Triage® Cardio ProfilER / Triage® Cardiac Controls

Indications For Use:

The Triage® Cardio ProfilER / Triage® Cardiac Controls are to be used with the Triage® Cardio ProfilER / Triage® Cardiac Panel and Triage® Meter to assist the laboratory in monitoring test performance.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K030089

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)