OCT - 3 2001

510(k) Summary of Safety and Effectiveness

Triage® TOX Drug Screen 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: (To be determined) K012999

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	9/4/01

B. Device Names

1. Trade Name

   Triage® TOX Drug Screen Controls

2. Common / Usual Name

   Not Applicable

3. Classification Name

   Quality Control Material (Assayed and Unassayed)
   21 CFR 862:3280
   Class I
   Product Code: DIF

C. Predicate Devices

BIO-RAD Liquicheck Urine Toxicology Controls (K981590, K970666)
Dade Behring Emit Calibrators/Controls (K935230)

D. Device Description and Intended Use

The Triage® TOX Drug Screen Controls are assayed materials to be used with the Triage® TOX Drug Screen and Triage® Meter to assist the laboratory in monitoring test performance.

E. Summary of Comparison Data

The table below provides a comparison of the technical principles between the Triage® TOX Drug Screen Controls and the predicate devices.

Characteristic	Triage® TOX Drug Screen Controls	Bio-Rad Liquicheck	Dade Behring Emit
Intended Use	Assayed control for monitoring urine-based drugs of abuse assays	Assayed control for monitoring urine-based drugs of abuse assays	Assayed control for monitoring urine-based drugs of abuse assays
Matrix	Human Urine	Human Urine	Human Urine
Form	Liquid	Liquid	Liquid
Analytes	Commonly abused drugs	Commonly abused drugs	Commonly abused drugs
Storage	-20 °C or colder	2-8 °C	2-8 °C

F. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 3 2001

Dr. Jeffrey R. Dahlen
Principal Scientist
Biosite Diagnostics, Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k012999
Trade/Device Name: Triage® TOX Drug Screen Controls
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: I, reserved
Product Code: DIF
Dated: September 5, 2001
Received: September 6, 2001

Dear Dr. Dahlen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): ~~(to be determined)~~ K012999

Device Name: Triage® TOX Drug Screen Controls

Indications For Use:

The Triage® TOX Drug Screen Controls are assayed materials to be used with the Triage® TOX Drug Screen 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)

Kena Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012999

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

(Optional Format 1-2-96)