

VIII. Safety and Effectiveness Summary

The STA®-Liatest® D-Di test kit is intended for use with STA® analyzers to perform quantitative assays of D-dimer antigen in citrated plasma by the immuno-turbidimetric method based on the measurement of light absorbance produced by a suspension of microlatex particles coated with specific mouse anti-human D-dimer monoclonal antibodies.

Each STA®-Liatest® D-Di test kit provides: 6 x 5-ml vials of ready-for-use Tris buffer and 6 x 6-ml vials of a suspension of microlatex particles coated with mouse anti-human D-dimer monoclonal antibodies.

Reagents in intact vials remain stable for 18 months after the date of manufacture, when stored at 2°-8°C. After opening of the vials, kit reagents (with STA®-Reducers and perforated caps installed on the vials) are stable for 15 days on board STA® analyzers.

The proposed STA®-Liatest® D-Di test kit has demonstrated substantial equivalence to the commercially available ASSERACHROM® D-Di kit (Diagnostica Stago, France; K862156) which is a microtiter ELISA-based procedure for the quantitative determination of D-dimer antigen levels in citrated plasma.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 26 1997

Andrew Loc B. Le., Ph.D.
• Director, Regulatory Affairs and Quality Assurance
American BioProducts Company
Five Century Drive
Parsippany, New Jersey 07054

Re: K964728
STA®-Liatest® D-Di Test Kit
Regulatory Class: II
Product Code: DAP
Dated: April 16, 1997
Received: April 18, 1997

Dear Dr. Le:

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 (for the indications for use stated in the enclosure) 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

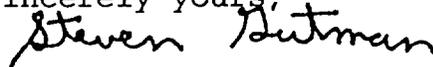
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

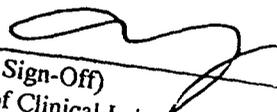
Enclosure

510(k) Number (if known): _____

Device Name: STA®-Liatest® D-Di Test Kit

Indications for Use:

The STA®-Liatest® D-Di test kit is intended for use with STA® analyzers (Diagnostica Stago, France: STA® full-size model, K942117; STA® Compact model, K961579) to perform quantitative determinations of D-dimer antigen levels in citrated plasma by the immuno-turbidimetric method based on the measurement of light absorbance produced by a suspension of microlatex particles coated with mouse anti-human D-dimer monoclonal antibodies.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K964728

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

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)