MAY 23 1997

K964718

VII. Safety and Effectiveness Summary

The STA® D-Di Calibrator is a citrated human plasma containing D-dimer at a known level, intended for use as a calibration plasma for the assay of D-dimer antigen by the immuno-turbidimetric method performed on STA® analyzers (Diagnostica Stago, France: STA® full-size model and STA® *Compact* model).

Each STA® D-Di Calibrator kit provides 6 x 1-ml vials of citrated human plasma in lyophilized form. The D-dimer value of each lot is indicated in the Assay Value insert supplied with each kit. The freeze-dried reagent in intact vials is stable for 24 months after the date of manufacture, when stored at 2°-8°C; the reconstituted plasma remains stable for 4 hours on board STA® analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 1997

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

Re: K964718
STA® D-Di Calibrator Kit
Regulatory Class: II
Product Code: DAP
Dated: March 12, 1997
Received: March 14, 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 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.

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 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):_____

Device Name: STA® D-Di Calibrator Kit

Indications for Use:

The STA® D-Di Calibrator kit is intended for use as a calibration plasma for D-dimer antigen assays by the immuno-turbidimetric method performed on STA® analyzers (Diagnostica Stago, France: STA® full-size model, K942117; STA® *Compact* model, K961579).

(Division Sign-Off)
Division of [illegible]evices
510(k) Number K964718

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

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

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

(Optional Format 1-2-96)