

NOV 12 1998

K983460

AMERICAN BIOPRODUCTS COMPANY
Premarket 510(k) Notification
STA-R® Automated Multi-Parametric Analyzer

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IX. SAFETY AND EFFECTIVENESS SUMMARY

The STA-R® instrument is a fully automatic laboratory analyzer designed to perform tests which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy. Once test samples and reagents are loaded onto the instrument, sample handling, reagent delivery, analysis and reporting of test results are performed automatically, making the STA-R® instrument a true "walk-away" system. A central processing unit controls instrument functions, including management of patient results, quality control, scheduling of instrument maintenance and workload organization.

The instrument utilizes Diagnostica Stago (France) reagents, and is open to adaptation of other reagents currently commercially available from third-party manufacturers. Bar-coding of test reagents, calibrators and controls facilitates their use on the system and makes reagent management simple. Manual entry of reagent information enables the utilization of non bar-coded reagents.

The instrument performs multiple test methodologies in random access (as selected by the user); these include clot-based tests and photometric assays at predetermined wavelengths.

Sample-to-sample carry-over has been demonstrated to be so low as to be undetectable.

The STA-R® instrument is substantially equivalent to the commercially available STA® analyzer, also from the same manufacturer (Diagnostica Stago, France), that received 510(k) clearance under K942117.



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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K983460
Trade Name: STA-R® Automated Multiparametric Analyzer
Regulatory Class: II
Product Code: JPA
Dated: September 30, 1998
Received: September 30, 1998

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 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). 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.

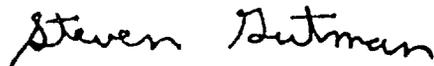
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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.

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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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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): K983460

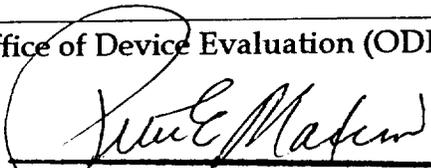
Device Name: STA-R® Automated Multi-Parametric Analyzer

Indications for Use:

STA-R® Automated Multi-Parametric Analyzer is a fully automatic clinical instrument designed for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

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

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



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983460

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)