

OCT 25 1999

K 992858

**510(k) Summary  
Abbott AxSYM® Homocysteine**

**Summary of Safety and Effectiveness Information Supporting a  
Substantially Equivalent Determination**

The following information as presented in the Premarket Notification [510(k)] for Abbott AxSYM Homocysteine constitutes data supporting a substantially equivalent determination.

AxSYM Homocysteine is a Fluorescence Polarization Immunoassay for the quantitative measurement of total L-homocysteine in human serum or plasma on the AxSYM System. AxSYM Homocysteine is calibrated with Abbott Homocysteine Calibrators. Abbott Homocysteine Controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM System.

Substantial equivalence has been demonstrated between the AxSYM Homocysteine assay and the Abbott IMx® Homocysteine assay. The intended use of both assays is for the quantitative measurement of total L-homocysteine. Both assays are automated, *in vitro*, competitive immunoassays that use antibodies specific for s-adenosyl-L-homocysteine. A least squares linear regression analysis between these two assays, using 300 specimens, yielded a correlation coefficient of 0.985, slope of 1.04 (95% confidence interval of 1.02 to 1.06), and y-axis intercept of -0.56  $\mu\text{mol/L}$  (95% confidence interval of -0.87 to -0.25). A Passing-Bablok linear regression analysis, using 300 specimens, yielded a correlation coefficient of 0.985, slope of 1.08 (95% confidence interval of 1.05 to 1.10), and y-axis intercept of -0.80  $\mu\text{mol/L}$  (95% confidence interval of -1.16 to -0.47).

In conclusion, these data demonstrate that the AxSYM Homocysteine assay is as safe and effective as, and is substantially equivalent to, the IMx Homocysteine assay.

Prepared and Submitted August 24, 1999 by:  
Margaret Prochniak  
Regulatory Specialist  
ADD Regulatory Affairs  
1-847-937-4106

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Department 9YC, Building AP31  
200 Abbott Park Road  
Abbott Park, IL 60064-6200



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**OCT 25 1999**

Ms. Margaret Prochniak  
Regulatory Specialist  
Abbott Laboratories  
ADD Regulatory Affairs  
Dept. 9YC, Bldg. AP 31  
200 Abbott Park Road  
Abbott Park, Illinois 60064-6200

Re: K992858  
Trade Name: Abbott AxSYM<sup>®</sup> Homocysteine  
Regulatory Class: II  
Product Code: LPS  
Dated: August 24, 1999  
Received: August 25, 1999

Dear Ms. Prochniak:

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.

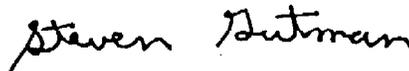
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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): K992858

Device Name: Abbott AxSYM® Homocysteine

Indications For Use:

The AxSYM® Homocysteine assay is a Fluorescence Polarization Immunoassay (FPIA) for the quantitative measurement of total L-homocysteine in human serum or plasma on the AxSYM System. Homocysteine values can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K992858

(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)