

JUN 24 1997

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

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

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

AxSYM Folate is an ion capture assay for the quantitative determination of folate in human serum, plasma, or red blood cells. AxSYM Folate is calibrated with Abbott Folate calibrators. Abbott Folate controls are assayed for the verification of the accuracy and precision of the AxSYM System.

Substantial equivalence has been demonstrated between the AxSYM Folate assay and the IMx® Folate assay. The intended use of both assays is for the quantitative determination of folate in human serum, plasma, or red blood cells. The dynamic ranges of the IMx Folate and AxSYM Folate assays are 0.82 to 20 ng/mL and 0.9 to 20 ng/mL respectively. A correlation analysis between these two assays is as follows:

Sample Type	n	Correlation Coefficient	Slope	Standard Error of Y Estimate	Y-Intercept (ng/mL)
Serum	261	0.979	0.991	0.864	0.5
Red Blood Cells	145	0.906	0.885	43.290	39.7

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

Prepared and Submitted June 13, 1997 by:

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JUN 24 1997

Food and Drug Administration
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Laura L. Granitz
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Abbott Park, Illinois 60064-3537

Re: K972232
Abbott AxSYM® Folate
Regulatory Class: II
Product Code: CGN
Dated: June 13, 1997
Received: June 16, 1997

Dear Ms. Granitz:

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.

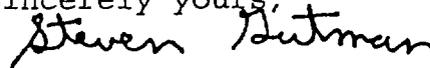
Page 2

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): K972232

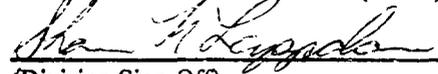
Device Name: Abbott AxSYM® Folate

Indications For Use:

Abbott AxSYM® Folate is an Ion Capture Assay intended to measure the vitamin folic acid in serum, plasma, and red blood cells. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

(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

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K972232
OR Over-The-Counter Use _____

(Optional Format 1-2-96)