K984301

FEB 5 1999

510(k) Summary
Abbott ARCHITECT™ Folate
Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

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

The ARCHITECT Folate assay is a Chemiluminescent Microparticle Folate Binding Protein assay for the quantitative determination of folate in human serum, plasma, (tripotassium EDTA, lithium heparin, or sodium heparin) and red blood cells (tripotassium EDTA). The ARCHITECT Folate assay is calibrated with Abbott ARCHITECT Folate Calibrators. Abbott ARCHITECT Folate Controls are assayed for the verification of the accuracy and precision of the Abbott ARCHITECT™ *i* System.

Substantial equivalence has been demonstrated between the ARCHITECT Folate assay and the BioRad Quantaphase II® Folate Radioassay. The intended use of the ARCHITECT Folate assay is for the quantitative determination of folate in human serum, plasma, and red blood cells. The intended use of the BioRad Quantaphase II® Folate Radioassay is for the quantitative determination of folate in human serum, plasma, and whole blood.

Sample	Regression Method	n	r	Slope (95%CI)	Intercept(95% CI)
Serum	Least Squares	333	0.927	0.97 (0.92, 1.01)	0.44 (0.02, 0.87)
	Passing-Bablok	333	0.927	1.08 (1.05, 1.12)	-0.18 (-0.47, 0.06)
Whole Blood	Least Squares	160	0.929	1.00 (0.94, 1.06)	36.04 (4.62, 67.46)
	Passing-Bablok	160	0.929	1.14 (1.09, 1.20)	-18.83 (-40.97, 3.59)

In conclusion, these data demonstrate that the ARCHITECT Folate assay is as safe and effective as, and is substantially equivalent to, the BioRad Quantaphase II® Folate Radioassay.

Prepared and Submitted December 1, 1998 by:
Laura Granitz
Senior Regulatory Specialist
1-847-938-0092

Abbott Laboratories
ADD Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064-3537

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 5 1999

Ms. Laura L. Granitz
Senior Regulatory Specialist
ADD Regulatory Affairs
Abbott Laboratories
Diagnostic Division
Dept. 9V6 Building AP31
200 Abbott Park Road
Abbott Park, Illinois 60064

Re: K984301
Trade Name: Abbott ARCHITECT™ Folate
Regulatory Class: II Product Code: CGN
II JIS
I JJX
Dated: January 20, 1999
Received: January 21, 1999

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 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.

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 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): K984301

Device Name: Abbott ARCHITECT™ Folate

Indications For Use:

The Abbott ARCHITECT™ Folate assay is a Chemiluminescent Microparticle Folate Binding Protein assay for the quantitative determination of folate in human serum, plasma, and red blood cells on the Abbott ARCHITECT™ *i* System. Measurements obtained by this device aid 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
510(k) Number K984301

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)