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510(k) Summary
Abbott ARCHITECT® Folate

K023397

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, and red blood cells. The ARCHITECT Folate assay is calibrated with ARCHITECT Folate Calibrators. 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 Bio-Rad Quantaphase II® B12/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 Bio-Rad Quantaphase II B12/Folate Radioassay is for the quantitative determination of folate in human serum, plasma, and whole blood. A correlation analysis between the two assays yielded the following results.

Sample	Regression Method	n	r	Slope	Intercept
Serum	Least Squares	241	0.904	0.93	1.4
	Passing-Bablok	241	0.904	1.05	-0.0
Whole Blood	Least Squares	244	0.904	1.05	-54.7
	Passing-Bablok	244	0.904	1.10	-69.9

n = number of specimens
r = correlation coefficient

In conclusion, these data demonstrate that the ARCHITECT Folate assay is as safe and effective as, and is substantially equivalent to, the Bio-Rad Quantaphase II B12/Folate Radioassay.

Prepared and Submitted October 4, 2002 by:

Margaret Prochniak 10/4/02

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Margaret Prochniak, M.S.
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200 Abbott Park Road
Abbott, IL 60064-6187

Re: k023397
Trade/Device Name: Abbott ARCHITECT® Folate
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CGN; JIS; JJX
Dated: October 4, 2002
Received: October 9, 2002

Dear Ms. Prochniak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Applicant: Abbott Laboratories

510(k) Number (if known): K 023397

Device Name: Abbott ARCHITECT® Folate

Indications For Use:

The ARCHITECT® Folate assay is a Chemiluminescent Microparticle Folate Binding Protein assay used for the quantitative determination of folate in human serum, plasma, and red blood cells on the ARCHITECT *i* System. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023397

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)