k092740

ARCHITECT Folate

510(k) Summary (Summary of Safety and Effectiveness)

MAR - 5 2010

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

Darla Abaño, Sr. Regulatory Administrator
Regulatory Affairs
Abbott Laboratories Diagnostics Division
Dept. 9V6 AP6C-2
100 Abbott Park Road
Abbott Park, IL 60064

Device Name:

Reagents:

Classification Name: Folic acid test system
Trade Name: ARCHITECT Folate
Common Name: Folate
Governing Regulation: 862.1295
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: CGN

Calibrators:

Classification Name: Calibrator, secondary
Trade Name: ARCHITECT Folate Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls:

Classification Name: Quality Control Material (assayed and unassayed)

Trade Name: ARCHITECT Folate Controls (Low, Medium, and High)

Common Name: Control

Governing Regulation: 862.1660

Device Classification: Class I

Classification Panel: Clinical Chemistry

Product Code: JJX

Legally marketed device to which equivalency is claimed:

Reagents predicate: AxSYM Folate (K972232)

Calibrators predicate: AxSYM Folate (K972232)

Controls predicate: AxSYM Folate (K972232)

Intended Use of Device:

The ARCHITECT Folate assay is a chemiluminescent microparticle Folate Binding Protein assay for the quantitative determination of folate in human serum and plasma on the ARCHITECT *i* System. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

Description of Device:

The ARCHITECT Folate assay is a two-step assay for the quantitative determination of folate in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology. Two pre-treatment steps mediate the release of folate from endogenous folate binding protein.

In Pre-Treatment Step 1, the sample and Pre-treatment Reagent 2 (Dithiothreitol or DTT) are aspirated and dispensed into a reaction vessel (RV). In Pre-Treatment Step 2, an aliquot of sample/Pre-Treatment Reagent 2 mixture is aspirated and

dispensed into a second RV. Pre-Treatment Reagent 1 (potassium hydroxide or KOH) is then added. An aliquot of the pre-treated sample is transferred into a third RV, followed by the addition of Folate Binding Protein (FBP) coated paramagnetic microparticles and assay specific diluent. Folate present in the sample binds to the FBP coated microparticles. After washing, pteroic acid-acridinium labeled conjugate is added and binds to unoccupied sites on the FBP coated microparticles. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). An inverse relationship exists between the amount of folate in the sample and the RLUs detected by the ARCHITECT *i* optical system.

Comparison of Technological Characteristics:

The ARCHITECT Folate assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of folate in human serum and plasma. The AxSYM Folate assay utilizes ion capture technology for the quantitative measurement of folate in human serum, plasma, and red blood cells (RBC).

Summary of Non-Clinical Performance:

The ARCHITECT Folate assay is substantially equivalent to the AxSYM Folate assay in terms of precision, linearity, interferences, and method comparison as demonstrated in the non-clinical performance data in this 510(k) submission.

The ARCHITECT Folate assay demonstrated substantially equivalent performance to the AxSYM Folate assay with correlation coefficients of 0.898 for serum samples. General bias in folate results between the two methods is due to the standardization differences listed in the Substantial Equivalence table. The predicate device utilizes standards based on gravimetric preparations of folic acid. The investigational assay has been standardized to accurately recover WHO Serum Folate International Standard (IS) 03/178.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Re: k092740
Trade Name: ARCHITECT Folate
Regulation Number: 21 CFR §862.1295
Regulation Name: Folate
Regulatory Class: Class II
Product Codes: CGN, JIT, JJX
Dated: March 3, 2010
Received: March 4, 2010

Dear Ms. Abano:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092740

Device Name: ARCHITECT Folate

Indications for Use:

Reagents

The ARCHITECT Folate assay is a chemiluminescent microparticle Folate Binding Protein assay for the quantitative determination of folate in human serum and plasma on the ARCHITECT *i* System. Folate measurements are used in the diagnosis and treatment of megaloblastic anemia.

Calibrators

The ARCHITECT Folate Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of folate in human serum and plasma.

Controls

The ARCHITECT Folate Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of folate in human serum and plasma.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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