K984108

FEB 3

510(k) Summary

Abbott ARCHITECT™ B12

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™ B12 constitutes data supporting a substantially equivalent determination.

The ARCHITECT B12 assay is a Chemiluminescent Microparticle Intrinsic Factor assay for the quantitative determination of vitamin B_{12} in human serum and plasma (tripotassium EDTA). The ARCHITECT B12 assay is calibrated with Abbott ARCHITECT B12 Calibrators. Abbott B12 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 B12 assay and the AxSYM® B12 Assay. The intended use of both assays is for the quantitative determination of vitamin B_{12} in human serum and plasma. A least squares linear regression analysis between these two assays, using 544 serum specimens, over the range of 60 to 2000 pg/mL, yielded a correlation coefficient of 0.956, a slope of 0.96 (95% Confidence Interval [CI] of 0.93 to 0.98), and an intercept of -27 pg/mL (95% CI of -42 to -12). Passing-Bablok linear regression analysis between these two assays gave a correlation coefficient of 0.956, a slope of 0.91 (95% CI of 0.89 to 0.93), and an intercept of -7 pg/mL (95% CI of -18 to 2).

In conclusion, these data demonstrate that the ARCHITECT B12 assay is as safe and effective as, and is substantially equivalent to, the AxSYM® B12 Assay.

Prepared and Submitted November 16, 1998 by:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 3 1999

Ms. Laura L. Granitz
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Diagnostic Division
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Re: K984108
Trade Name: Abbott ARCHITECT™ B12
Regulatory Class: II
Product Code: LIG
Dated: November 16, 1998
Received: November 17, 1998

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): K984108

Device Name: Abbott ARCHITECT™ B12

Indications For Use:

The Abbott ARCHITECT™ B12 assay is a Chemiluminescent Microparticle Intrinsic Factor assay for the quantitative determination of B12 in human serum and plasma on the Abbott ARCHITECT™ *i* System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984108

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)