AUG 3 - 2005

K051327

510(k) Summary

Abbott AxSYM® 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 AxSYM B12 constitutes data supporting a substantially equivalent determination. Substantial equivalence has been demonstrated between the Abbott AxSYM B12 assay and the Abbott ARCHITECT® B12 assay. The intended use for both assays is for the quantitative determination of vitamin B_{12} in human serum or plasma.

The AxSYM B12 assay is a Microparticle Enzyme Intrinsic Factor assay for the quantitative determination of vitamin B_{12} in human serum or plasma. The AxSYM B12 assay is calibrated with Abbott B12 Calibrators. Abbott B12 Controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM System.

A correlation analysis between the AxSYM B12 and the ARCHITECT B12 assay yielded the following results.

Regression Method	n	r	Slope	Intercept
Least Squares	441	0.98	1.09	3.7
Passing-Bablok			1.12	-13.9

n = number of specimens
r = correlation coefficient

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

Prepared and Submitted 19 May 2005 by:

Margaret Prochniak 5/19/05

Margaret Prochniak, M.S.
Senior Regulatory Affairs Specialist
ADD Regulatory Affairs
Phone: (847) 937-4106
Fax: (847) 937-9616
E-mail: Margaret.Prochniak@abbott.com

Abbott Laboratories
Diagnostics Division
Department 9VA, Building AP4A-3
100 Abbott Park Road
Abbott Park, IL 60064-6095

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 - 2005

Ms. Margaret Prochniak, M.S.
Sr. Regulatory Affairs Specialist
ADD Regulatory Affairs
Abbott Laboratories
Diagnostics Division
Department 9VA, Building AP4A-3
100 Abbott Park Road
Abbott Park, IL 60064-6095

Re: k051327
Trade/Device Name: Abbott AxSYM® B12 Reagent
Abbott AxSYM® B12 Specimen Diluent
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: CDD
Dated: May 19, 2005
Received: May 20, 2005

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 (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K051327

Device Name: Abbott AxSYM® B12 Reagent
Abbott AxSYM® B12 Specimen Diluent

Indications For Use:

The AxSYM B12 reagent is a microparticle enzyme intrinsic factor assay for the quantitative determination of vitamin B_{12} in human serum or plasma on the AxSYM System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

The AxSYM B12 Specimen Diluent is used for manually diluting specimens for testing using the AxSYM B12 assay.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051327