DEC 16 2005

K053330

Special 510(k) Summary
Abbott ARCHITECT® B12 Calibrators

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter's Name and Address: Abbott Laboratories
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Date Prepared: 29 November 2005

Device Proprietary Name:	Abbott ARCHITECT® B12 Calibrators
Device Common Name:	Vitamin B12
Classification Number:	Clinical Chemistry, 21 CFR §862.1750
Predicate Device:	Abbott ARCHITECT® B12 510(k) Number: K984108 Concurrence Date: 3 February 1999
Device Description:	The Abbott ARCHITECT B12 Calibrators are liquid, ready-for-use materials in a buffered aqueous solution. Concentrations of the calibrator components span the dynamic range of the assay.
Intended Use:	The Abbott ARCHITECT B12 Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum and plasma.

A correlation analysis was performed between the ARCHITECT B12 6-Point Calibrators and the ARCHITECT 2-Point Calibrators. In this evaluation, serum specimens tested ranged from 76 to 1944 pg/mL by the ARCHITECT B12 6-point calibration assay, and from 77 to 1988 pg/mL by the ARCHITECT B12 2-point calibration assay. The evaluation yielded the following results:

Regression Method	N	r	Slope	Intercept
Least Squares	495	0.998	0.96	22
Passing-Bablok	495	0.998	0.98	12

n = number of specimens
r = correlation coefficient

In conclusion, these data demonstrate that the performance of the Abbott ARCHITECT B12 6-point calibrators is acceptable and comparable to the performance of the predicate device, when used according to its intended use.

Prepared and Submitted 29 November 2005 by:

Margaret Prochniak 11/29/05

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Dept. 9VA, Bldg. AP 6C-2
100 Abbott Park Road
Abbott Park, IL 60064-6095

Re: k053330
Trade/Device Name: Abbott ARCHITECT® B12 Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 29, 2005
Received: December 1, 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,

Alberto Gutierrez, 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): K 053330

Device Name: Abbott ARCHITECT® B12 Calibrators

Indications For Use:

The Abbott ARCHITECT B12 Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum and plasma.

Prescription Use __X___ **OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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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

510(k) K053330