K112443

DEC 19 2011

510(k) Summary

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

Submission correspondent:

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The Technology Park
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Device Name: ARCHITECT Active-B12 (Holotranscobalamin) Reagents, ARCHITECT Active-B12 (Holotranscobalamin) Calibrators (A-F) and ARCHITECT Active-B12 (Holotranscobalamin) Controls (Low and High).

Reagents:

Classification Name: Vitamin B12 test system

Trade Name: ARCHITECT Active-B12 (Holotranscobalamin)

Common Name: Holotranscobalamin test

Governing Regulation: 862.1810

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: CDD

Calibrators:

Classification Name: Calibrator

Trade Name: ARCHITECT Active-B12 (Holotranscobalamin) 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 Active-B12 (Holotranscobalamin) Control

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:

AxSYM Active-B12 (HoloTC) Immunoassay (k062467)

Intended Use of Device:

The ARCHITECT Active-B12 (Holotranscobalamin) assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of Holotranscobalamin in human serum on the ARCHITECT *i* System. Active-B12 (Holotranscobalamin) is used as an aid in the diagnosis and treatment of vitamin B12 deficiency.

Description of Device:

The ARCHITECT Active-B12 (Holotranscobalamin) assay is a two-step immunoassay for the quantitative determination of Holotranscobalamin in human serum using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-holotranscobalamin coated paramagnetic microparticles are combined. Holotranscobalamin present in the sample binds to the anti-holotranscobalamin coated microparticles. After washing, anti-transcobalamin acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pretrigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of Holotranscobalamin in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:

ARCHITECT Active-B12 (Holotranscobalamin) and AxSYM Active-B12 (HoloTC) are both automated immunoassays for the quantitative determination of Holotranscobalamin (HoloTC).

The ARCHITECT and AxSYM systems differ in their detection methods; the ARCHITECT is a chemiluminescent microparticle immunoassay (CMIA) whereas the AxSYM is a microparticle enzyme immunoassay (MEIA).

Summary of Non-Clinical Performance:

The ARCHITECT Active-B12 (Holotranscobalamin) assay is substantially equivalent to the AxSYM Active-B12 (HoloTC) assay in terms of precision, calibration, linearity on dilution and specificity as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT Active-B12 (Holotranscobalamin) assay demonstrated substantially equivalent performance to the AxSYM Active-B12 (HoloTC) assay as indicated by a method comparison study.

The ARCHITECT Active-B12 (Holotranscobalamin) assay demonstrated substantially equivalent performance to the AxSYM Active-B12 (HoloTC) as indicated by a method comparison with a correlation coefficient (r) of 0.94 (95% confidence interval 0.92, 0.96) for the 125 samples tested and covering the range of 8.13 to 124.43 pmol/L Holotranscobalamin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Axis-Shield Diagnostics Ltd
c/o Dr. Simon Richards
The Technology Park
Luna Place
Dundee, DD2 1XA,UK

DEC 19 2011

Re: k112443
Trade Name: ARCHITECT Active-B12 (Holotranscobalamin) Reagents,
ARCHITECT Active-B12 (Holotranscobalamin) Calibrators (A-F),
ARCHITECT Active-B12 (Holotranscobalamin) Controls (Low and High)
Regulation Number: 21 CFR §862.1810
Regulation Name: Vitamin B12 test system.
Regulatory Class: Class II
Product Codes: CDD, JIT, JJX
Dated: November 25, 2011
Received: November 29, 2011

Dear Dr. Richards:

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

Enclosure

Indication for Use

510(k) Number (if known): k112443

Device Name:

ARCHITECT Active-B12 (Holotranscobalamin) Reagents, ARCHITECT Active-B12 (Holotranscobalamin) Calibrators (A-F) and ARCHITECT Active-B12 (Holotranscobalamin) Controls (Low and High)

Indication For Use:

Reagents:

The ARCHITECT Active-B12 (Holotranscobalamin) assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of Holotranscobalamin in human serum on the ARCHITECT *i* System. Active-B12 (Holotranscobalamin) is used as an aid in the diagnosis and treatment of vitamin B12 deficiency.

Calibrators:

The ARCHITECT Active-B12 (Holotranscobalamin) Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of Holotranscobalamin in human serum.

Controls:

The ARCHITECT Active-B12 (Holotranscobalamin) Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System (reagents, calibrators and instrument) when used for the quantitative determination of Holotranscobalamin in human serum.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) K112443