APR 24 2008

**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.

The assigned 510(k) number is: k073640

## Submission correspondent:

Dr Claire Dora
Regulatory Affairs Officer
Axis-Shield Diagnostics, Ltd.
The Technology Park
Dundee DD2 1XA, UK
Telephone: +44 13 82 422000
Date prepared: December 19, 2007

## Device Name: ARCHITECT Homocysteine

## Reagents:

Classification Name: Urinary Homocystine (Nonquantitative) Test System
Trade Name: ARCHITECT Homocysteine
Common Name: Homocysteine Enzyme Immunoassay
Governing Regulation: 21 CFR 862.1377
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: LPS

## Calibrators:

Classification Name: Calibrator, Secondary
Trade Name: ARCHITECT Homocysteine Calibrators
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

## Controls:

Classification Name: Single (specified) analyte controls (assayed and unassayed)
Trade Name: ARCHITECT Homocysteine 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 Homocysteine Assay; K992858.

## Intended Use of Device:

The ARCHITECT Homocysteine assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of total L-homocysteine in human serum or plasma on the ARCHITECT *i* System.

Homocysteine values can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

## Description of Device:

The ARCHITECT Homocysteine assay is a one-step immunoassay for the quantitative determination of total L-homocysteine in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex. Bound or dimerised homocysteine (oxidized form) is reduced by dithiothreitol (DTT) to free homocysteine, which is then converted to S-adenosyl homocysteine (SAH) by the action of the recombinant enzyme S-adenosyl homocysteine hydrolase (rSAHHase) in the presence of excess adenosine. The SAH then competes with acridinium-labeled S-adenosyl cysteine for particle-bound monoclonal antibody. Following a wash stage and magnetic separation, pre-trigger and trigger solutions are added to the reaction mixture and the resulting chemiluminescence is measured as relative light units (RLUs). An indirect relationship exists between the amount of homocysteine in the sample and the RLUs detected by the ARCHITECT *i* System optics.

## Comparison of Technological Characteristics:

ARCHITECT Homocysteine and AxSYM Homocysteine are both automated immunoassays for the quantitative determination of total L-homocysteine in human serum or plasma.

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

## Summary of Non-Clinical Performance:

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

## Summary of Clinical Performance:

The ARCHITECT Homocysteine assay demonstrated substantially equivalent performance to the AxSYM Homocysteine indicated by a method comparison study.

Passing-Bablok linear regression method comparison was performed on 456 plasma samples in the range of 3.70 to 49.94 µmol/L. The ARCHITECT Homocysteine versus AxSYM Homocysteine gave a slope of 0.98 (95% Confidence interval 0.97 to 1.00) and an intercept of -0.74 (95% Confidence interval -0.99 to -0.54). ARCHITECT Homocysteine versus AxSYM Homocysteine gave an r value of 0.98 (95% Confidence interval 0.98 to 0.99).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 24 2008

Axis-Shield Diagnostics, Ltd.
c/o Dr. Claire Dora
Acting Regulatory Affairs Manager
Luna Place, The Technology Park
Dundee, DD2 1XA, Scotland
United Kingdom

Re: k073640
Trade/Device Name: ARCHITECT Homocysteine Reagents, ARCHITECT Homocysteine Calibrators, and ARCHITECT Homocysteine Controls
Regulation Number: 21 CFR 862.1377
Regulation Name: Urinary homocystine (non-quantitative) test system.
Regulatory Class: II
Product Code: LPS, JIT, JJX
Dated: March 13, 2008
Received: March 17, 2008

Dear Dr. Dora:

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

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): k073640

Device Name: AR CHITECT Homocysteine Reagents, ARCHITECT Homocysteine Calibrators and ARCHITECT Homocysteine Controls

Indication For Use:

Reagents:
The ARCHITECT Homocysteine assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of total L-homocysteine in human serum or plasma on the ARCHITECT *i* System. Homocysteine values can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Calibrators:
The ARCHITECT Homocysteine Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of total L-homocysteine in human serum or plasma.

Controls:
The ARCHITECT Homocysteine 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 total L-homocysteine in human serum or plasma.

For in vitro diagnostic use.

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)

Carol C. Benson

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

510(k) K073640