K071525

MAR 19 2008

510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary:	May 31, 2007 Updated March 17, 2008
Device Trade or Proprietary Name:	Activated Aspartate Aminotransferase
Device Common/Usual Name or Classification Name:	Activated AST
Classification Number/Class:	Class II / 862.1100
Product Code:	CIT

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 862.1100.

The assigned 510(k) number is: K071525

Test Description:

Abbott Laboratories Activated AST is an in vitro diagnostic assay for the quantitation of aspartate aminotransferase (also known as serum glutamic oxaloacetic transferase or SGOT) in human serum or plasma. The Abbott Laboratories Activated AST assay is a clinical chemistry assay in which the aspartate aminotransferase catalyzes the transfer of the amino group from *L*-aspartate to α-ketoglutarate, in the presence of pyridoxal-5'-phosphate, forming oxaloacetate and *L*-glutamate. Oxaloacetate in the presence of NADH and malate dehydrogenase (MDH) is reduced to *L*-malate. In this reaction, the NADH is concomitantly oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.

Substantial Equivalence:

The Abbott Laboratories Activated AST assay on the Abbott AEROSET and ARCHITECT *c*Systems is substantially equivalent to the Abbott AST Activated (K981221) assay on the AEROSET System. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays use NADH (with P-5'-P) methodology
- Both assays can be used for the quantitation of AST
- Both assays yield similar results
- Both assays use serum and plasma

Differences:

Abbott Laboratories Activated Aspartate Aminotransferase is a liquid reagent. Aspartate Aminotransferase Activated is a lyophilized reagent requiring reconstitution prior to use.

Intended Use:

The Abbott Laboratories Activated AST assay is used for the quantitation of aspartate aminotransferase in human serum or plasma. Aspartate Aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET and ARCHITECT *c*Systems. The Abbott Laboratories Activated AST assay, LN 08L91, method comparison yielded acceptable correlation between the following reagent/instrument comparisons:

1. Abbott Laboratories Activated AST assay on the AEROSET vs. Abbott AST Activated (K981221) on the Abbott AEROSET System (Predicate Device).

2. Abbott Laboratories Activated AST on the ARCHITECT *c*8000 vs. Abbott AST Activated (K981221) on the Abbott AEROSET System (Predicate Device).

3. Abbott Laboratories Activated AST on the ARCHITECT *c*16000 System vs. Abbott AST Activated (K981221) on the Abbott AEROSET System (Predicate Device).

Results consisted of:

1. The Abbott Laboratories Activated AST assay on the Abbott AEROSET System showed a correlation coefficient of 0.999, slope of 1.06, and Y-intercept of -3.79 U/L when compared to the Predicate Device.

2. The Abbott Laboratories Activated AST on the ARCHITECT *c*8000 System showed a correlation coefficient of 0.999, slope of 1.01, and Y-intercept of –4.15 U/L when compared to the Predicate Device.

3. The Abbott Laboratories Activated AST on the ARCHITECT *c*16000 System showed a correlation coefficient of 0.999, slope of 1.03, and Y-intercept of –3.75 U/L when compared to the Predicate Device.

The Abbott Laboratories Activated AST assay run on the Abbott AEROSET and ARCHITECT *c*Systems method comparison results yielded acceptable correlation to the Abbott AST Activated assay on the Abbott AEROSET System.

Precision studies were conducted using the Abbott Laboratories Activated AST assay. On the ARCHITECT *c*8000 System, the 20 Day total %CV for Level 1 (43 U/L) is 4.5%, and Level 2 (192 U/L) is 1.0% and the 5 Day total %CV for Level 3 (23 U/L) is 2.4% and Level 4 (3,437 U/L) is 0.7%. On the AEROSET System, the 5 Day total %CV for Level 1 (46 U/L) is 2.3% and Level 2 (205 U/L) is 0.7%. On the ARCHITECT *c*16000 System, the 5 Day total %CV for Level 1 (45 U/L) is 1.8% and Level 2 (197 U/L) is 0.5%.

The Abbott Laboratories Activated AST assay is linear up to 1,985 U/L. The limit of quantitation of the Abbott Laboratories Activated AST assay is 5 U/L, with Flex Rate linearity up to 5,364 U/L.

These data demonstrate that the performance of the Abbott Laboratories Activated AST assay is substantially equivalent to the performance of the Abbott AST Activated assay, LN 08D37 (K981221) on the AEROSET and ARCHITECT *c*Systems.

Conclusion:

The Abbott Laboratories Activated AST assay on the AEROSET System and ARCHITECT *c*Systems is substantially equivalent to the Abbott AST Activated assay, LN 08D37 (K981221) on the AEROSET System and ARCHITECT *c*Systems as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Abbot Laboratories
c/o Ms. Linda Morris
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Irving, TX 75038

MAR 19 2008

Re: k071525
Trade/Device Name: Next Generation Activated Asparate Aminotransferase Assay
Regulation Number: 21 CFR 862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system.
Regulatory Class: Class II
Product Code: CIT
Dated: March 10, 2008
Received: March 11, 2008

Dear Ms. Morris:

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) 276-0490. 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

Indications for Use

510(k) Number (if known): K071525

Device Name: Abbott Laboratories Activated Aspartate Aminotransferase

Indications For Use:

Activated Aspartate Aminotransferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate aminotransferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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