K041811

SEP 1 0 2004

510(k) Summary

Abbott AxSYM® Troponin-I *ADV*

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 Troponin-I *ADV* constitutes data supporting a substantially equivalent determination.

The AxSYM Troponin-I *ADV* assay is a Microparticle Enzyme Immunassay for the quantitative determination of cardiac troponin-I in human serum or plasma. The AxSYM Troponin-I *ADV* assay is calibrated with AxSYM Troponin-I *ADV* Standard Calibrators. AxSYM Troponin-I *ADV* Controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM System.

Substantial equivalence has been demonstrated between the AxSYM Troponin-I *ADV* assay and the Beckman Coulter™ Access® AccuTnI assay. The intended use of the AxSYM Troponin-I *ADV* assay is for the quantitative determination of cardiac troponin-I in human serum or plasma. The intended use of the Beckman Coulter Access AccuTnI assay is for the quantitative determination of cardiac troponin I in human serum and plasma. A correlation analysis between the two assays yielded the following results.

Regression Method	n	R	Slope	Intercept
Passing-Bablok (All Specimens)	546	0.97	1.47	-0.05
Passing-Bablok (*ADV* Dynamic Range)	531	0.95	1.47	-0.05

n = number of specimens
r = correlation coefficient

In conclusion, these data demonstrate that the AxSYM Troponin-I *ADV* assay is as safe and effective as, and is substantially equivalent to, the Beckman Coulter Access AccuTnI assay.

Prepared and Submitted 31 August 2004 by:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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SEP 1 0 2004

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Re: k041811
Trade/Device Name: Abbott AxSYM® Troponin-I *ADV*
Abbott AxSYM® Troponin-I *ADV* Standard Calibrators
Abbott AxSYM® Troponin-I *ADV* Controls
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JIT, JJX,
Dated: July 2, 2004
Received: July 6, 2004

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

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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

ATTACHMENT 1

Indications for Use

510(k) Number (if known): K041811

Device Name: Abbott AxSYM® Troponin-I *ADV*
Abbott AxSYM® Troponin-I *ADV* Standard Calibrators
Abbott AxSYM® Troponin-I *ADV* Controls

Indications For Use:

The AxSYM Troponin-I *ADV* assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of cardiac troponin-I (cTnI) in human serum or plasma on the AxSYM System. Troponin-I values are used to assist in the diagnosis of myocardial infarction (MI)

The AxSYM Troponin-I *ADV* Standard Calibrators are for the standard calibration of the AxSYM System when used for the quantitative determination of cardiac troponin-I in human serum or plasma.

The AxSYM Troponin-I *ADV* Controls are for the estimation of test precision and the detection of systematic analytical deviations of the AxSYM System (reagents, calibrators, and instrument) when used for the quantitative measurement of cardiac troponin-I in human serum or plasma.

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)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041811