K974103

NOV 25 1997

Section II

510(k) Summary

510(k) Summary
Abbott AxSYM® Troponin-I

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 constitutes data supporting a substantially equivalent determination.

AxSYM Troponin-I is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of cardiac troponin-I in human serum or plasma. AxSYM Troponin-I is calibrated with Abbott Troponin-I Calibrators. Abbott Troponin-I Controls are assayed for the verification of the accuracy and precision of the AxSYM System.

Substantial equivalence has been demonstrated between the AxSYM Troponin-I assay and the Dade® Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay.

The intended use of the AxSYM Troponin-I assay is for the quantitative determination of cardiac troponin-I in serum or plasma. Troponin-I values are used to assist in the diagnosis of acute myocardial infarction (AMI).

The intended use of the Stratus Cardiac Troponin-I assay is for the quantitative determination of cardiac troponin-I levels in serum and plasma. Cardiac troponin-I determinations aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Both assays are automated, *in vitro* immunoassays that use antibodies specific for the cardiac isotype of troponin-I. The fluorescent signal measured by both assays is directly proportional to the concentration of cardiac troponin-I in the sample. A Passing-Bablok linear regression analysis between these two assays, using 158 specimens, yielded a Spearman correlation coefficient of 0.851, a slope of 3.42 ng/mL, and Y-axis intercept of -1.09 ng/mL.

In a multi-center clinical study, a total of 246 patients, representing 689 observations, were followed with serial sampling to rule-in or rule-out for AMI. Clinical diagnosis was based upon the World Health Organization (WHO) criteria for AMI. There were 49 patients who ruled-in for AMI. Using 2.0 ng/mL as a diagnostic cutoff, the AxSYM Troponin-I assay demonstrated a clinical sensitivity of 93.9% and a clinical specificity of 93.4%.

In conclusion, these data demonstrate that the AxSYM Troponin-I assay is as safe and effective as, and is substantially equivalent to the Dade Stratus Cardiac Troponin-I Fluorometric Enzyme Immunoassay.

Prepared and Submitted October 30, 1997 by:
Laura Granitz
Senior Regulatory Specialist
ADD Regulatory Affairs
1-847-938-0092
Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-3537

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 1997

Laura Granitz
Senior Regulatory Specialist
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Re: K974103
Abbott AxSYM® Troponin-I
Regulatory Class: II
Product Code: MMI
Dated: October 30, 1997
Received: October 31, 1997

Dear Ms. Granitz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974103

Device Name: Abbott AxSYM® Troponin-I

Indications For Use:

Abbott AxSYM® Troponin-I is a Microparticle Enzyme ~~Immunoassay (MEIA)~~ for the quantitative determination of cardiac troponin-I in human serum or plasma on the Abbott AxSYM System. Measurements obtained by this device are used to assist in the diagnosis of acute myocardial infarction (AMI).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974103