DEC - 6 1999

K993353

510(k) Summary of Safety and Effectiveness Information

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

Sponsor: Gabriel Muraca, Manager RA
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
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Phone: 914-524-3494
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Device Name: Bayer Immuno 1™ System Troponin I Method

Classification Name: Immunoassay Method

Predicate Device: Bayer Immuno 1™ System Troponin I Method

Device Description:

The proposed Bayer Immuno 1™ Troponin I assay is an enzyme label sandwich assay using a monoclonal and polyclonal antibody. A Troponin I specific monoclonal antibody is labeled with fluorescein and a Troponin I specific goat affinity purified antibody is labeled with alkaline phosphatase (ALP). The solid phase consists of a suspension of magnetizable particles coated with antibody to fluorescein (mIMP reagent). Sample or calibrator, R1 reagent containing fluorescein-antibody conjugate, R2 reagent containing ALP-antibody conjugate and mIMP reagent are mixed and incubated at 37° C. In the presence of Troponin I a (fluorescein-conjugate:Troponin I:ALP-conjugate) complex is formed and captured by the anti-fluorescein antibodies on the magnetic particles. The particles are washed and para-nitrophenyl phosphate substrate solution is added. The ALP in the antibody conjugate reacts with the substrate to form para-nitrophenoxide and phosphate. Increasing absorbance due to the formation of para-nitrophenoxide is monitored at 405 nm and 450 nm. The dose response curve is directly proportional to the concentration of Troponin I in the sample. A linear point to point fit is used to construct the dose response curve. The Bayer Immuno 1 Troponin I assay has a range of 0 to 200 ng/mL and liquid calibrators are provided with values of 0,5,10,20,60, and 200 ng/mL Troponin I.

The Bayer Immuno 1Troponin I Assay was previously cleared under Document Control No. K973616. The proposed Bayer Immuno 1 Troponin I Assay is substantially equivalent in technical performance and intended use to the FDA cleared device. Changes are limited to modifications in the indications for use. The additional indication for use is:

...in the risk stratification of patients with non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction or increased probability of ischemic events requiring urgent revascularization procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K993353
Trade Name: Troponin I Assay for the Bayer Immuno 1™ System
Regulatory Class: II
Product Code: MMI
Dated: September 30, 1999
Received: October 5, 1999

Dear Mr. Muraca:

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 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). 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/dsma/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):

Device Name: **Troponin I**

Indications For Use:

This *in vitro* diagnostic method intended to quantitatively measure the concentration of cardiac Troponin 1 (Tn1) in human serum and plasma (lithium heparin) using the Bayer Immuno 1 system. When used in conjunction with other clinical data, such as presenting symptoms and diagnostic procedures, measurements of cardiac Tnl aids in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with non-ST segment-elevation, acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revalcularization procedures.

This diagnostic method is not intended for use on any other system.

(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 Formal 1-2-96

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K040335